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EVALUATION

on the Targeted evaluation of Regulation (EU)2017/745 on Medical Devices and Regulation (EU)2017/746 on In vitro Diagnostic Medical Devices

Accompanying the document

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

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List of acronyms and abbreviations

AIMDD	Active Implantable Medical Devices Directive
CE	Conformité Européenne
CFE	Call for Evidence
CIE	Clinical Investigation and Evaluation
DG	Directorate-General
DG SANTE	Directorate-General for Health & Food Safety
EFTA	European Free Trade Association
EQ	Evaluation Questions
EQM	Evaluation Questions Matrix
EU	European Union
EUDAMED	European database on medical devices
EUR	Euro
HIV	Human Immunodeficiency Virus
IA	Impact Assessment
IMDRF	International Medical Device Regulators Forum
IVD	*In Vitro* Diagnostic Medical Devices
IVDD	*In Vitro* Diagnostic Medical Device Directive
IVDR	*In Vitro* Diagnostic Medical Device Regulation
JAT	Joint Assessment Team
MD	Medical Device
MDD	Medical Device Directive
MDR	Medical Device Regulation
MS	Member State
NANDO	New Approach Notified and Designated Organisations
NB	Notified Body
NCAR	National Competent Authorities Report
QMS	Quality Management System
SME	Small and medium enterprises
SWD	Staff Working Document
UDI	Unique device identification

1. INTRODUCTION

Medical devices and *in vitro* diagnostic medical devices (IVDs) have a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease. There are over 2 000 000 medical technologies in Europe[1]. Examples of medical devices are sticking plasters, contact lenses, X-ray machines, pacemakers, breast implants, software apps and hip replacements. IVDs are used to perform tests on samples, and examples include HIV blood tests, pregnancy tests and blood sugar monitoring systems for diabetics. Moreover, around two thirds of all clinical decisions are based on information provided by IVDs[2]. In 2025, the European medical device market is estimated at approximately 170 bn EUR, making it the second largest in the world following the US[3]. Europe has a positive medical devices trade balance of 5 bn EUR (2024) with more than 930 000 people employed in this industry in Europe (2025).

In the EU, medical devices and IVDs are regulated by Regulation (EU) 2017/745 on medical devices (MDR)[4] and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)[5]. Hereafter, these two Regulations are referred to jointly as 'the Regulations'. They were adopted in 2017 and aim to ensure that only safe and performant devices are on the EU market, to protect patient safety and public health while supporting innovation. They aim to create a robust, transparent and sustainable legal framework, aligned with international practices, improving clinical safety and fair market access.

Considering the extent of the changes introduced by the Regulations, transition periods were envisaged to ensure a smooth transition to the new rules for legacy devices[6]. The transition periods continue to apply and have been extended several times due to challenges in the implementation of the Regulations. These include mitigating the risk of shortages, and delays in the deployment and mandatory use of the European database on medical devices (EUDAMED). These challenges were further exacerbated by the impact of the COVID-19 pandemic, which particularly affected clinical investigations, onsite audits and global supply chains. In view of the significant challenges encountered during this transition, while an evaluation is legally required by May 2027, the Commission launched a targeted evaluation of the Regulations in 2024.

Purpose of the evaluation

The targeted evaluation assesses the performance of the Regulations with a view to providing a basis for reflections on future actions. Focus is placed on their impact on the availability of devices, including devices for small populations (e.g. 'orphan devices') and

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[1] World Health Organization, https://www.who.int/europe/news-room/fact-sheets/item/health-technologies.
[2] Rohr, U-P., et al., 'The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report', *PLOS ONE*, 11(3): e0149856, 2016, https://doi.org/10.1371/journal.pone.0149856.
[3] MedTech Europe website, *Facts and Figures 2025* (Europe includes EU-27, the UK, Norway, Switzerland).
[4] Regulation (EU) 2017/745, OJ L 117, 5.5.2017, pp. 1–175, ELI: http://data.europa.eu/eli/reg/2017/745/oj.
[5] Regulation (EU) 2017/746, OJ L 117, 5.5.2017, pp. 176–332, ELI: https://eur-lex.europa.eu/eli/reg/2017/746/oj/eng.
[6] See MDCG, *MDCG 2021-25 Rev.1*, October 2024: on the application of MDR requirements to 'legacy devices'.

innovative devices. An important focus is also given to costs and administrative burdens, especially for SMEs, as well as the benefits arising from the legislation.

Covering all evaluation criteria (effectiveness, efficiency, coherence, relevance, EU added value), the evaluation considers whether the objectives of the Regulations have been achieved or can be achieved by the end of the extended transition periods, taking into account the current regulatory framework and the ways of implementing it. It also assesses the efficiency of the Regulations and the cost benefit balance, and their coherence including with other EU legislation. It analyses the relevance of the Regulations and whether they are "fit for purpose" to meet the current and future needs of both patients and stakeholders. It will also assess the added value of acting at EU level.

While the Regulations have not been fully implemented yet, several signals have pointed to some potential systemic challenges affecting market availability, legal certainty, and competitiveness, among others. This evaluation therefore intends to assess whether the regulatory framework is on track to achieve its objectives within the extended transitional period, to identify any systemic inefficiencies or inconsistencies that may require further monitoring and to inform future policy decisions and potential for simplification.

Scope of the evaluation

This evaluation covers the period between the adoption of the legislation (5 April 2017) and 31 December 2024[7]. It covers both the basic acts as well as implementing and delegated acts[8] adopted during this timeframe. It performs an assessment of the provisions of the Regulations that were implemented or for which the implementation process had been initiated during this timeframe. The geographical scope of the evaluation covers the implementation of the Regulations on the 'Union market', namely in the 27 EU Member States, the three European Economic Area (EEA) countries and Türkiye[9]. It also examines activities carried out based on bilateral agreements and multi-lateral cooperation (primarily the International Medical Device Regulators Forum (IMDRF)), and their impacts on safety, availability and trade.

Methodology and data

The evaluation has been designed on the basis of an evaluation matrix (*Annex III*) which operationalises the five evaluation criteria into a series of evaluation questions. It draws on a broad evidence base but given that no single source is complete or fully representative, the evaluation applies triangulation, including a scoring system to synthesise findings. The *ex-post* analysis is subject to several limitations that need to be considered when

[7] When available, data from 2025 was also used in the context of the targeted evaluation.
[8] European Commission website, *Medical Devices – Sector – New Regulations*.
[9] European Commission website, *'Notice to stakeholders' EU-Turkey Customs Union Agreement in the field of medical devices'*, March 2022.

interpreting the results. *Annex II* presents the methodology applied, its robustness and limitations.

2. WHAT WAS THE EXPECTED OUTCOME OF THE INTERVENTION?

2.1. Description of the intervention and its objectives

2.1.1. Background to intervention (i.e. move from Directives to Regulations)

The Regulations were introduced to replace the previous regulatory framework consisting of three Directives[10] in place since the 1990s, as they were found to have multiple problems that undermined the main objectives of the Directives, i.e. the safety of medical devices, their free circulation within the internal market and issues arising from insufficient data and information on medical devices. The intervention logic (*Figure 1*) is a reconstruction of the logic at the time of the adoption of the Regulations in 2017. It consists of the problems identified under the Directives, the drivers that led to these problems and their consequences. It outlines the objectives of the introduced Regulations, as well as the expected inputs and outputs to achieve the expected results and impacts.

Several policy options addressing problems identified in the 2012 Impact Assessment[11] that accompanied the legislative proposals were reflected in the Regulations. Problems included 'challenge to the uniform interpretation and implementation of the legal requirements as well as to the coordination of the activities of the national competent authorities' and differences in the designation and monitoring of notified bodies, leading to 'an uneven level of protection of the patients, users and public health' (see further *section 2.1.2*). The introduction of the Regulations was closely linked to the objectives of the Third EU Health Programme (2014-2020)[12], namely objective III (contribute to innovative, efficient and sustainable health systems) and objective IV (facilitate access to better and safer healthcare for EU citizens). The Regulations introduced key health policy goals outlined in the wider health programme (see *section 2.1.3*).

2.1.2. Problems identified under the previous regulatory framework

For the purpose of this evaluation, the 7 problems identified in the Impact Assessment[13] have been re-defined into three major problems (see *Figure 2 Revised intervention logic – Drivers & Problems*):

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[10] Council Directive 90/385/EEC, OJ L 189, 20.7.1990, pp. 17–36, ELI: http://data.europa.eu/eli/dir/1990/385/oj; Council Directive 93/42/EEC, OJ L 169, 12.7.1993, pp. 1–43, ELI: http://data.europa.eu/eli/dir/1993/42/oj; Council Directive 98/79/EC, OJ L 331, 7.12.1998, pp. 1–37, ELI: http://data.europa.eu/eli/dir/1998/79/oj.

[11] European Commission, *Staff Working Document Impact Assessment on the revision of the regulatory framework for medical devices*, 2012. ERL: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=swd:SWD_2012_0273.

[12] Regulation EU 282/2014, OJ L 86, 21.3.2014, pp. 1–13, ELI: http://data.europa.eu/eli/reg/2014/282/oj.

[13] The problems identified: **(1)** Oversight of notified bodies, **(2)** Post-market safety, **(3)** Regulatory status of products, **(4)** Lack of transparency and harmonised traceability, **(5)** Access to external expertise, **(6)** Unclear and insufficient obligations and responsibilities of economic operators, including in the fields of diagnostic services and internet sales, **(7)** Management of the regulatory system.

Problem 1 – Insufficient safety of some medical devices

By late 2011, the medical device EU regulatory framework faced intense scrutiny from both the media[14] and the political spheres[15], in particular after findings that *Poly Implant Prothèse* (PIP) used for breast implants had, over several years, been manufactured with industrial silicone instead of medical grade silicone contrary to the notified body's approval, resulting in harm to thousands of women around the world. Safety issues were also identified with other medical devices, such as certain metal-on-metal hip joint replacements[16,17] or urogynaecological surgical meshes[18,19]. These safety issues pointed to insufficient clinical data having been collected for some devices, a lack of involvement of scientific expertise in regulatory processes, an insufficient level of oversight of notified bodies, insufficient reporting of manufacturers in the post market phase using a harmonised set of criteria, and a lack of coordination between Member States on safety issues.

Problem 2 – Obstacles to the functioning of the internal market

In addition to the 27 EU Member States, the four European Free trade Agreement (EFTA) countries and Türkiye also adopted the Directives, creating a single market of 32 countries. This posed challenges for implementation, enforcement of legal requirements and coordination among national authorities. The internal market was fragmented for several reasons, including imprecise legal requirements on the designation and monitoring[20] of notified bodies by competent authorities and a lack of requirements for medical devices without an intended medical purpose, to determine borderline[21] cases, and medical device classification issues. There was also a misalignment between the medical device regulatory framework and the new horizontal framework for product legislation. These were in part attempted to be remedied by exchange of views and coordination of activities of national competent authorities in informal and non-statutory working groups and the production of guidance documents. As the participation in the groups was voluntary and the guidance documents not legally binding, it was found that they are not suitable to enforce a high level of patient safety and the functioning of the internal market.

Problem 3 – Insufficient and incoherent data and information on medical devices

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[14] See for example: Reuters, *Special Report: The French breast implant scandal*, 2 February 2012.
[15] European Parliament Resolution of 14 June 2012: P7_TA-PROV(2012)0262 (2012/2621(RSP)).
[16] BfArM website, Field Safety Notice for the DePuy metal-on-metal join replacements (August 2010).
[17] SCENIHR, *Safety of Metal-on-Metal joint replacements with a particular focus on hip implants*, Expert Opinion, 24 September 2014.
[18] U.S. Food and Drug Administration (FDA), *Urogynecologic surgical mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse*, July 2011.
[19] SCENIHR, *Safety of surgical meshes used in urogynaeocological surgery*, Expert Opinion, 3 December 2015
[20] Of note: Implementing Regulation (EU) 920/2013 OJ L 253, 25.9.2013, pp. 8–19, ELI: http://data.europa.eu/eli/reg_impl/2013/920/oj introduced clearer legally binding requirements on the designation and monitoring of notified bodies designated to assess medical devices (excludes IVDs).
[21] 'Borderline products' are those where it is not clear from the outset whether they fall under the Medical Devices Regulation. See for instance: MDCG Document, *MDCG 2022 – 5 Rev. 1*, October 2024.

Due to the limited scope of the European databank on medical devices[22] (Eudamed 2) which was not publicly accessible[23] and the absence therefore of a comprehensive central database regarding medical devices available on the EU market, stakeholders, in particular users, claimed a lack in transparency. This prompted several Member States to impose registration systems both in terms of databases and introduce traceability requirements on economic operators, including the regional use of Unique Device Identification systems in some cases, in order to have more information on devices put into service within their territory. These national measures hampered the establishment a European level overview of CE (European Conformity) marked devices placed on the internal market and were in part incompatible with one another, not allowing traceability across borders and creating burdens for economic operators that had to comply with multiple sets of requirements when placing products on the markets of different Member States.

As a consequence of the three problems described above, the regulatory framework provided an uneven level of protection of the patients, users and public health. Moreover, it lowered the confidence in the CE marking which should guarantee the free movement of devices within the EU, and which is also recognised by several non-EU countries as proof of compliance with their own national safety requirements (*Figure 2 – Consequences*). Moreover, an underlying regulatory fragmentation in the system was also identified as a problem at the time. This could be understood as both a problem in itself, and as further compounding the above-described problems by hampering coordination and harmonisation of competent authorities for medical devices, which in turn disrupted the smooth functioning of the internal market and impacts the safety of devices in the market.

2.1.3. Objectives and expected impacts of the new regulatory framework (i.e. Regulations)

Although significant issues were found with the Directives, the findings did not imply that the European medical device regulatory system was fundamentally flawed. As such, the Regulations adopted by the European co-legislators maintained the overall objectives of ensuring a high level of protection of health for patients and users and a smooth internal market, as well as providing a regulatory framework that supports innovation and competitiveness and fosters transparency on medical devices for citizens and actors (*Figure 2 – General objectives*) and built on the existing systems in place (*Figure 2 – Specific objectives*).

To achieve these objectives, the Regulations foresaw that financial, human and institutional resources would be inputted at Member State and European level (*Figure 2 - Expected input*) and that a number of actions would be put into place (*Figure 2 - Expected output*) across the lifecycle of a medical device/IVD to create a robust, transparent, predictable, and sustainable regulatory framework at European level. The regulatory framework to be established under the Regulations is described represented in *Figure* -

[22] Eudamed 2 (link is no longer available).
[23] See SWD(2012) 273 final, section 2.2.4.

Expected outputs and changes introduced across the device lifecycle in *Figure 1*. These changes range from strengthening already existing requirements (e.g. on clinical evidence) and incorporating existing elements that were previously not legally binding into the legal act (e.g. post-market surveillance), to introducing new elements into the regulatory infrastructure at European level (e.g. expert panels, EU reference laboratories, UDI, EUDAMED with six interconnected modules and some available to citizens/patients).

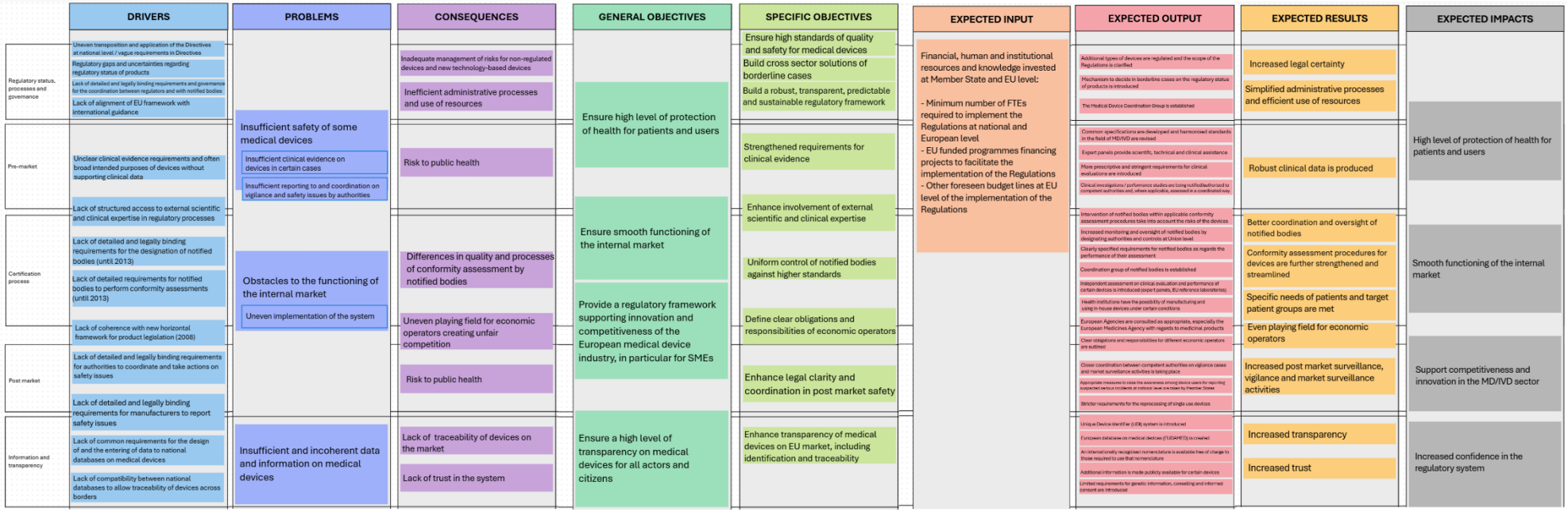
Nevertheless, some of the above changes to the regulatory framework come with inherent trade-offs. These trade-offs include the strengthening of requirements (e.g., clinical evidence or post-market surveillance requirements and notified body oversight), with expected increase in regulatory burden for most actors in the system; and increased harmonisation and reinforced governance systems, implying enhanced coordination and more resources. In this context, the Regulations contribute to the implementation of United Nations Sustainable Development Goals (UN SDGs) adopted in 2015[24]. In particular, it is expected that safe and performant devices contribute to SDG 3 and SDG 9. In materialising the expected inputs and outputs, the Regulations aim to achieve long-term impacts that are expected to be reached once the Regulations are fully implemented (*Figure 2 - Expected impacts*) and results that are expected to be reached in the medium-term, during the implementation of the Regulations (*Figure 2 - Expected results*).

Figure 1 - *Lifecycle of a medical device/IVD (source: Technopolis[25])*

[24] United Nations, *The 17 Goals*, UN website. SDG 3: Ensuring healthy lives and promote well-being for all at all stages; SDG 9: Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation.

[25] Technopolis, *Study supporting the targeted evaluation of the MDR and IVDR - Final report*, December 2025, under preparation.

Figure 2 – Revised intervention logic



2.2. **Point(s) of comparison**

Before the adoption of the Regulations in 2017, data on the EU regulatory system for medical devices and IVDs was limited and fragmented. Most available figures originate from the 2012 Impact Assessment with evidence gathered between 2006 and 2012. Due to the lengthy period between the intervention's development and its gradual implementation, these data are indicative. They provide an approximate picture of the situation under the Directives and the conditions that motivated regulatory reform. This serves as a contextual baseline for assessing subsequent developments under the Regulations.

The point of comparison for this evaluation covers the period between the drafting of the 2012 Impact Assessment, when the Regulations were designed, and the start of their gradual implementation from 2017 onwards. It therefore spans a broader timeframe than a single reference year, reflecting both the situation under the Directives and the transition to the new framework. Taking into account the expected evolution in the absence of the intervention is not feasible due to the lack of consistent data and the long delay between policy design and implementation. In addition, the adopted Regulations differ significantly from the proposed acts, necessitating a cautious interpretation of the 2012 supporting impact assessment. Furthermore, the medical devices sector has been influenced by external factors including the COVID-19 pandemic and related global supply chain disruptions and changing patterns of medical consumption and innovation. Consequently, observed changes in key indicators (see *Annex III*) cannot be interpreted solely in quantitative terms. They require careful qualitative assessment of which developments can reasonably be attributed to the Regulations themselves.

Many stakeholders (e.g., healthcare professionals, patients, Health Technology Assessment (HTA) bodies, among others) indicated that the regulatory framework under the Directives lacked **transparency**[26]. It was particularly underlined that there was no access to data on several aspects, including medical devices' characteristics, clinical data, and their conformity assessment pathways. In addition, Eudamed 2, at the time, was limited to some information on class I devices and neither the public nor healthcare professionals, had access. Furthermore, these safety crises occurring at that time had largely hampered the **level of trust** in the regulatory systems and devices in the political scene[27].

Under the Directives, the designation, oversight and performance of notified bodies varied significantly across Member States. National authorities and manufacturers pointed to major differences in how notified bodies conduct **conformity assessments** – particularly in the depth and quality of their evaluation of manufacturers' **clinical evidence** and in the use of tools such as unannounced inspections or product checks. **Notified bodies** themselves acknowledged such inconsistencies, which led to uneven levels of patient safety and distorted competition between manufacturers[28]. Furthermore, some evidence

[26] See SWD (2012) 273 final, page 19.
[27] See SWD (2012) 273 final, page 10 and the European Parliament Resolution of 14 June 2012 (note 15, page 5).
[28] See SWD (2012) 273 final, page 15.

(e.g. surveys in the clinical technical working group) indicated an increase in pre-market clinical investigations following the 2007/47/EC amendments, which was potentially linked to reinforced requirements. However, comparable EU-wide data were not available, as some national competent authorities did not provide figures while others aggregated data for clinical investigations and IVD performance evaluations.

The EU market for medical devices under the Directives was characterised by a broader **device availability** and generally faster access to new technologies compared to other major markets. Studies at the time indicated that while EU patients could access innovative and complex devices several years earlier than U.S. patients, this advantage sometimes came at the cost of insufficient pre-market evidence and subsequent product withdrawals[29]. Despite these trends, comparable data on market entry timelines, device withdrawals, or competitive dynamics across Member States were limited, constraining the assessment of how far the Directives ensured a truly **level playing field** or balanced **innovation** with patient safety.

Before the Regulations, **vigilance** and **post-market surveillance** were fragmented and inconsistently applied across Member States, leading to significant variation in the detection and management of risks. Moreover, there were no consolidated statistics allowing for an overall assessment of device safety across the EU, and most incidents did not lead to regulatory measures, often due to insufficient investigation capacity[30]. As a result, the framework under the Directives provided only a partial picture of device performance and safety, limiting early detection of emerging risks and delaying coordinated responses at EU level.

3. HOW HAS THE SITUATION EVOLVED OVER THE EVALUATION PERIOD?

3.1. Current state of play

The MDR and IVDR entered into force in May 2017 and have been in application since May 2021 and May 2022, respectively. However, so far, implementing the Regulations has been challenging, resulting in the need to amend the transitional period for existing devices (see s*ections 1* and *3.2*). Despite implementation delays, unexpected factors and some unintended effects of the Regulations, progress has been made in several areas.

3.2. Implementation progress

Unexpected factors: the COVID-19 pandemic prompted a one-year delay (with the exception of some provisions) in the MDR's application[31] to allow authorities, health institutions and manufacturers focus on the unprecedented crisis to health systems and ensure supply of critical devices. These resource-intensive activities significantly impacted

[29] Regulation of Medical Devices in the United States and European Union, Daniel B. Kramer, M.D., Shuai Xu, M.Sc., and Aaron S. Kesselheim, M.D., J.D., M.P.H. DOI: 10.1056/NEJMhle1113918, VOL. 366 NO. 9.
[30] See SWD (2012) 273 final, page 16.
[31] Regulation (EU) 2020/561, OJ L 130, 24.4.2020, pp. 18–22, ELI: http://data.europa.eu/eli/reg/2020/561/oj.

MDR implementation in the subsequent years, thereby indirectly affecting IVDR implementation from 26 May 2022 (see *section 4.1.1.6*).

Unintended effects: as stakeholders have reported challenges in meeting strengthened requirements and capacity constraints, leading to the risk of shortages and disappearance of critical devices from the market (particularly niche and orphan devices for small populations), several transitional measures have been introduced (see also *section 4.1.1*).

Legislative (amendments): implementation challenges, exacerbated by the COVID-19 pandemic, led to unforeseen amendments to the Regulation's **transitional provisions**. The **MDR** transitional period was extended across all device classes (see *Annex VII*, *Figure 7* and *8*[32]): to December 2027 for high-risk devices, December 2028 for medium risk devices. These extended transition periods were however subject to several conditions[33]. The legislative amendments also removed the sell-off period[34] for legacy devices. Similarly, **the IVDR** transitional periods were extended twice[35,36], to December 2027 for high-risk IVDs, December 2028 for medium-risk IVDs, and December 2029 for lower-risk IVDs, under conditions akin to the MDR. Overall, this staggered approach by risk class aims to manage the workload on notified bodies, ensuring patient access to safe devices while mitigating the risk of shortages and minimising negative business impacts including on innovation. **EUDAMED's modules** for mandatory use have also been gradually rolled out to mitigate the consequences of development delays[37]36. In addition, an **advance warning mechanism for supply interruptions and discontinuations** was introduced[38] (see *section 4.1.1.3*).

Legislative (implementing and delegated acts): under the Regulations, the Commission holds a significant number of empowerments for implementing and delegated acts[39]. Whilst not all have been exercised, they have so far proved an essential simplification tool to respond to progress in the fast-evolving medical devices sector and overall facilitate an efficient implementation of the Regulations. These include novelties of the MDR applying to products without a medical intended purpose (such as dermal fillers), and simplification measures, such as the possibility for healthcare professionals to also receive the manufacturer's instructions for use in electronic format[40], establishing expert panels on orphan devices[41], as well as common specifications[42]. Planned measures include the expansion of the list of well-established technologies (WET)[43] and on the uniform

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[32] *Figure 7* and *8* in Annex VII explain the risk classification of devices under the MDR and IVDR respectively.
[33] Regulation (EU) 2023/607, OJ L 80, 20.3.2023, pp. 24–29, ELI: http://data.europa.eu/eli/reg/2023/607/oj.
[34] This removed the need to dispose of safe medical devices that are already on the market but not yet with the final user.
[35] Regulation (EU) 2022/112, OJ L 19, 28.1.2022, pp. 3–6, ELI: http://data.europa.eu/eli/reg/2022/112/oj.
[36] Regulation (EU) 2024/1860, OJ L, 2024/1860, 9.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1860/oj.
[37] See note 35, page 11.
[38] See note 35, page 11.
[39] See note 8, page 3.
[40] Commission Implementing Regulation (EU) 2025/1234, OJ L, 2025/1234, 26.6.2025, ELI: http://data.europa.eu/eli/reg_impl/2025/1234/oj.
[41] European Commission website, *Medical Devices – Expert panels*.
[42] European Commission website, *Medical Devices – In Vitro Diagnostics – Common specifications*.
[43] European Commission website, *Medical devices – expansion of the list of well-established technologies*.

application of requirements for notified bodies[44]. In addition, in October 2025, 38 harmonised standards (which provide manufacturers with a presumption of conformity to the requirements of the Regulations) are available (36 under the MDR and 17 under the IVDR).[45]

Governance and coordination: a number of coordination structures have been formalised or newly established[46]. **At the European level** (See *Annex VII, Figure 1*), the European Commission has regulatory, policy and audit responsibilities in coordinating the implementation of the Regulations. The European Commission's Joint Research Centre[47] provides scientific support and coordinates the selection procedure for the EU reference laboratories (EURLs). The European Medicines Agency (EMA)[48] is involved in providing scientific and clinical support through expert panels[49]. **At the national level**, Member States have duly designated competent authorities[50] responsible for implementing the Regulations, who are also appointed to the Medical Device Coordination Group (MDCG) and its 13 technical sub-groups, chaired by the European Commission[51]. Finally, **notified bodies**[52] are third-party entities, either public or private, designated to carry out conformity assessment activities for medium and high-risk devices and issue relevant certificates. The Regulations have also established the Notified Body Coordination Group (NBCG-Med[53]) to enhance notified body coordination in the de-centralised certification system.

In addition, a pilot for the **coordinated assessment of clinical investigations and performance studies** across multiple Member States, supported by the European Commission was launched in February 2025[54]. Building on this, the **COMBINE programme**[55] looks at coordinated assessment of clinical investigations and performance studies, combined with clinical trials of medicinal products.

Scientific structures: expert panels[56] serve to provide scientific, technical and clinical advice relating to medical devices and IVDs, as well as provide opinions on clinical evaluation by notified bodies for certain high-risk medical devices and IVDs**.** In 2025, there are a total of 12 thematic panels for MDs and 1 for IVDs. For **EURL designations**, the first set of EURLs was designated in 2023 covering four categories of high-risk IVDs.

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[44] European Commission website, *Medical devices –uniform application of the requirements for notified bodies*.
[45] European Commission website, *Medical Devices – Topics of Interest – Harmonised standards*.
[46] European Commission website, *Medical Devices – Sector - Coordination and Governance*.
[47] Commission Implementing Regulation (EU) 2023/2713, OJ L, 2023/2713, 6.12.2023, ELI: http://data.europa.eu/eli/reg_impl/2023/2713/oj.
[48] European Medicines Agency website, *Medical device expert panels*.
[49] JRC, *Handover of expert panels on medical devices and in vitro diagnostics from the Commission's Joint Research Centre (JRC) to the European Medicines Agency (EMA)*, News article, 3 March 2022.
[50] National competent authorities are designated by Member States in accordance with Article 101 MDR.
[51] European Commission website *Medical Devices - Dialogue between interested parties – Medical Device Coordination Group Working Groups*.
[52] European Commission website, *Medical Devices – Topics of Interest – Notified bodies for medical devices*.
[53] European Commission website, *Medical Devices - Dialogue between interested parties – Overview - Notified Body Coordination Group (NBCG-Med)*.
[54] European Commission website, *Medical Devices – Clinical investigations and performance studies - Pilot coordinated assessment for CI/PS*.
[55] European Commission website, *Medical Devices – Topics of Interest - The COMBINE programme*.
[56] European Commission website, *Medical Devices – Expert Panels - Overview*.

In 2025 another call for EURLs has been launched in two waves[57] to cover additional categories.

Notified bodies & Conformity assessment: as of October 2025, the NANDO system lists 51 MDR-designated notified bodies and 19 IVDR-designated bodies, with 12 MDR and 6 IVDR designation applications pending (See further *section 4.1.1.2*).

Transparency and traceability: the **Unique Device Identification (UDI) system**[58] requires all Regulation-compliant devices to be assigned, labelled and registered in EUDAMED, with a unique alphanumeric code. Applicable to all device risk classes, this system ensures that devices are uniquely identifiable and traceable in the EU, enhancing safety monitoring and healthcare digitalisation[59]. In addition, the **European Medical Device Nomenclature (**EMDN)[60], has been set up and provides a freely accessible nomenclature for use by manufacturers across compliance documentation and for EUDAMED device registration. It also serves various stakeholders like patients, researchers and practitioners, support transparency by providing key descriptions of devices available on the market and their categorisation. There have been **delays in the development and mandatory use of the six EUDAMED modules**[61]. EUDAMED aims to prevent multiple national registrations and to facilitate market monitoring. It is currently being developed in collaboration with the MDCG. Three modules have been available for voluntary use Actors (2020), UDI/Devices and notified bodies/Certificates (2021) which are being used by more than 85 000 users (manufacturers, notified bodies, public authorities, healthcare professionals, other actors[62]). Along with the Market Surveillance module, they will be mandatory to use from 28 May 2026, with the vigilance module to be made available after and the Clinical investigations/Performances studies module still under development.[63]

Non-legislative: Over 100 MDCG guidance documents have been published, and the Commission has funded numerous activities under the EU4Health Programme, to support the implementation of the Regulations.[64] These range from market monitoring activities, to enhancing certification efficiencies and supporting innovation, such as the 'NoBoCap –

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[57] See note 47, page 12.

[58] European Commission website, *Medical Devices – Topics of Interest - Unique Device Identifier - UDI - UDI Issuing Entities*. Article 27 MDR establishes the UDI system.

[59] European Commission, *Unique Device Identification (UDI) System under the EU medical devices Regulations 2017/745 and 2017/746*, 2020.

[60] European Commission website, *Medical Devices – Topics of Interest - European Medical Devices Nomenclature (EMDN)*.

[61] See *Annex VII Figure 2*.

[62] European Commission website, *EUDAMED working group under the MDCG*.

[63] Commission Decision (EU) 2025/2371, OJ L, 2025/2371, 27.11.2025ELI: http://data.europa.eu/eli/dec/2025/2371/oj, see also European Commission website, *EUDAMED roadmap*.

[64] European Commission website, *EU4Health annual work programmes*.

(Notified Body Increased Capacity) and the horizon scanning projects[65]. Recently to address shortcomings in the system, the MDCG is also working on non-legislative short-term actions, such as guidance on breakthrough technologies, certificates under conditions and on orphan IVDs to facilitate more efficient implementation[66].

4. EVALUATION FINDINGS (ANALYTICAL PART)

The evaluation questions covering all evaluation criteria are presented in *Annex III*.

4.1. To what extent was the intervention successful and why?

4.1.1. Effectiveness

A broad set of indicators were identified in relation to the general objectives of the Regulations. For the purpose of the analysis, they were grouped into **five sections** containing responses to several sub-evaluation questions (1) Legal certainty, transparency and trust; (2) Notified bodies, conformity assessments and clinical evidence; (3) Market functioning and level playing field; (4) Post-market surveillance and vigilance, and (5) Simplification and streamlined procedures. This grouping ensures thematic coherence and reflects functional linkages (e.g. notified body designation being linked to implementation of conformity assessment and clinical evidence requirements). Details on the grouping and scoring system used for each section are presented in *Annex II, sections 2.2 and 3.2* and more detailed evidence for each section is presented in *Annex VI scoring Tables 1 – 5* along with a final score per evaluation criterion in *Annex VI scoring Table 6*.

4.1.1.1.Legal certainty, transparency and trust

Legal certainty, trust, and transparency are closely interlinked – clear definitions and consistent application build predictability, while transparency tools provide the information base that supports both. At the time of the adoption, the Regulations were expected to deliver a high and uniform level of legal certainty, ensure transparency on medical devices for all actors and citizens, and strengthen trust among stakeholders. As of 2025, these objectives have been only partially achieved: while the legislative framework has enhanced clarity and consistency compared to the Directives, persistent gaps in implementation have limited predictability, transparency, and trust in the system (see negative score in *Annex VI, Table 1*). Perceptions of unclear requirements and divergent interpretations across Member States and notified bodies limit predictability and hinder the smooth functioning of the internal market. While the Regulations have laid important

[65] Nobocap, BRINGING TOGETHER EUROPE TO UNLOCK MEDICAL DEVICE REGULATIONS & THE AI ACT FOR INNOVATORS AND SMES IN EUROPE, October 2025. URL: https://nobocap.eu/ and Hadea, EU4Health prior information notice: horizon scanning system for medical devices & in vitro diagnostic medical devices, 3rd June 2024. Url: https://hadea.ec.europa.eu/news/eu4health-prior-information-notice-horizon-scanning-system-medical-devices-vitro-diagnostic-medical-2024-06-03_en.

[66] European Commission website, MDCG minutes September meeting.

foundations for transparency and trust through public and stakeholder access to information, their full potential remains unrealised, and implementation poses challenges.

*To what extent has the MDR/IVDR **increased legal certainty** for stakeholders (definitions, procedures, consistency of application)?*

Evidence shows that so far fewer **national legal disputes** in which a court decision was taken have been reported under the Regulations (2018 – 2024) compared to the Directives (2014 – 2021). One Member State reported a particularly notable decrease in national legal disputes, from 77 under the MDD/AIMDD to just 2 under the MDR/IVDR. As for **disputes between manufacturers and notified bodies on device classification**, few national decisions have been reported respectively under MDR (23) and IVDR (3) across 9 countries, with outcomes being split between manufacturers and notified bodies opinions[67]. For medical devices, this can be compared to 167 decisions reported across 11 countries under the MDD/AIMDD from 2014 – 2021. However, no causal link can be inferred between the number of legal disputes and legal certainty; fewer disputes may result from other factors, such as greater awareness of reporting mechanisms or external factors, such as cost of legal disputes and timelines for decisions in particular legal systems.

The **guidance** volume under the Regulations is high, with over 100 MDCG guidance documents & FAQs[68] issued since 2017 which were expected to facilitate implementation. Stakeholders have however reported on-going challenges with clarity and consistency in the Regulation's implementation, including unclear definitions, inconsistent interpretations by notified bodies and national authorities and vague or impractical guidance[69]. Only 40% of public consultation respondents believe MDCG guidance brings legal clarity[70] and 112 out of 324 stakeholders responding to the Call for Evidence called for clearer, binding guidance and stronger alignment across Member States to reduce ambiguity and ensure predictability[71]. Evidence therefore suggests that operational legal certainty remains limited.

The Regulations introduced various EU level **procedures** including on classification disputes and product qualification, aiming to enhance legal certainty[72]. So far, these procedures have not been used. Furthermore, implementation experience of non-binding procedures has shown ineffectiveness. For instance, the 'Helsinki procedure' to determine

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[67] Targeted national competent authority survey, conducted in the context of the Targeted Evaluation of the MDR/IVDR. Hereafter 'Targeted national competent authority survey'.

[68] European Commission website, *Medical Devices – Sector - New Regulations- Guidance - MDCG endorsed documents and other guidance*. These guidance documents are non-legally binding.

[69] Position papers, Call for evidence, Reality check workshop with manufacturers.

[70] European Commission website, *public consultation – EU rules on medical devise and in vitro diagnostics – targeted evaluation*. Hereafter 'Public consultation': 41.2% agree for MDR and 39.8% for IVDR.

[71] European Commission website, *call for evidence – EU rules on medical devices and in vitro diagnostics – targeted evaluation* . Hereafter 'Call for evidence'. 112 respondents: 48 from Company/Business, 20 from Health Providers, 18 from Business Associations, 10 from EU Citizens, 6 from Academic/Research Institutions, 4 from NGOs, 4 from Other, 2 from Public Authorities.

[72] Classification disputes: Article 52(3) and (4) MDR, Article 47(3) and (4) IVDR. Qualification matters: Article 4 MDR.

borderline and qualification issues[73] is too lengthy (average duration 347 days)[74], due to insufficient human resources and the lack of mandatory outcomes leading to low Member State participation in coordination. The qualitative evidence suggests that, while the Regulations have improved the legislative framework, operational clarity and harmonisation remain insufficient. Overall, increased consistency in interpretations and application of the Regulations by actors across Member States, as well as targeted improvements[75] are needed for the Regulations to realise their full potential for legal certainty and support a smooth functioning of the internal market.

*To what extent have the Regulations **improved transparency** for stakeholders?*

The Regulations have introduced several **public information requirements and tools** to improve transparency on medical devices. Information at EU level has increased through EUDAMED, providing for the first time a centralised EU data repository on economic operators, devices, and UDI registrations, as well as public access to reports. Although it was projected in 2017 that EUDAMED would be fully operational and mandatory between 2022 and 2024, implementation remains incomplete, its data accessibility and usability—and thereby transparency—are still limited for economic operators, healthcare professionals, patients, and users. This stems primarily from the gradual implementation process rather than the design of the regulatory framework.

EUDAMED **public information and traceability mechanisms** have been introduced to improve device safety monitoring and align with technical progress. These include requirements for manufacturers to publish Summaries of Safety and Clinical Performance (SSCPs) for high-risk and implantable devices, and for national designating authorities of notified bodies to publish summaries of monitoring reports. Publication should occur in EUDAMED once relevant modules are available for mandatory use. So far, compared to expectations in 2017, SSCP publication rates (by other means) appear low[76], whilst most countries with MDR/IVDR notified bodies have published summary monitoring reports[77].

On **traceability**, the UDI system will allow devices to be uniquely identifiable, traceable and monitored throughout the life cycle. It will provide a complete overview of devices on the Union market and safety information for users. Until UDI is fully applied to all devices

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[73] *Exchange of information between medical device competent authorities on borderline and classification cases Helsinki Procedure 2021*, version 23 June 2021.

[74] European Commission, internal sources.

[75] Call for Evidence – 324 respondents: 119 Company/Business from, 55 from Health Providers, 44 from EU Citizens, 35 from Business Associations, 21 Other, 17 from Academic/Research Institutions, 10 from non EU-citizens, 8 from NGOs, 6 From Public Authorities, 3 from Trade Unions, 3 from Patient Organisations, 2 from Notified Bodies, 1 from Consumer Organisations.

[76] e.g. publication via manufacturer websites. 'Economic operator survey' conducted in the context of the Targeted Evaluation of the MDR and IVDR, hereafter 'Economic operator survey': for pre-market clinical information, SS(C)P and clinical investigation: for MDs, less than half of the clinical investigation reports and summaries are published; for IVDs, only 0.4% of performance studies reports and summaries are published.

[77] European Commission website, *Medical Devices – Topics of Interest – Notified Bodies* - *Member States summaries of the national designating authority annual reports - 2024* (18 out of the 20 countries that have Notified Bodies submitted the MDR summary, and 7 of 12 submitted the IVDR summary).

on the market[78], the benefits of the system cannot yet fully be realised. Stakeholders welcome the UDI system, as an important step towards traceability, though 22 out of 121 of respondents noted challenges in its governance, rigidity, and delayed implementation[79]. In this regard, experience with UDI implementation experience has shown a need for adaptations in the system, particularly to accommodate identifications solutions for highly individualised devices[80]. Flexibility for future such accommodations could be considered.

The gradual rollout[81] of **EUDAMED** the key tool to facilitate enhanced transparency and traceability requirements is progressing (see *section 3.2. Implementation progress)*. Although data remains incomplete until EUDAMED's mandatory use, centralised public information on devices, i.e. the number of devices, certificates and actors registered has increased. Stakeholders identify the lack of a fully operational EUDAMED as a central obstacle to transparency, with its completion and improved functionality being a top priority[82]. They also pointed to the resulting limited access to public information and incomplete share of data, thus highlighting the gaps in transparency[83].

Overall, in terms of the Regulations achieving transparency and traceability objectives stakeholder perceptions remain mixed. Whilst these objectives are widely supported, frustrations persist about the lack of usable outputs in the regulatory system so far. More than 75% of public consultation respondents disagreed and strongly disagreed that a "robust, transparent, predictable and sustainable" regulatory framework exists[84], citing limited SSCP availability and non-transparent notified body processes. On the same note, healthcare professionals highlighted insufficient transparency in clinical data[85], and on notified body processes, including unclear timelines and fees[86][83]. Stakeholders show broad support for enhancing transparency and traceability through EUDAMED, UDI, and public access to clinical data, recognising the importance of these tools even though evidence on their impact remains limited[87]. Patients' perspectives in addition, were positive with over 65% of respondents to the Public Consultation agreeing they have access to information on devices and their use[88].

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[78] The MDR/IVDR UDI requirements, are only applicable to Regulation compliant devices, and not 'legacy devices' in transition. MDCG 2021-25 Rev. 1 Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC. Only when the EUDAMED functionality for UDI registration is mandatory and transition period ends, will UDI be fully applied to all devices.

[79] Call for Evidence – 22 out of 121 respondents: 7 Business, 6 Health Providers, 5 Business Associations, 2 EU Citizens, 1 NGO, 1 Other.

[80] European Commission website, *MDCG 2025-7 Position Paper Timelines MUDI-DI*.

[81] Regulation (EU) 2024/1860 OJ L, 2024/1860, 9.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1860/oj

[82] Call for Evidence – 34 out of 121 respondents: 10 Business, 8 Health Providers, 6 Business Associations, 4 EU Citizens, 3 NGOs, 2 Academics, 1 Public Authority.

[83] Position papers.

[84] Public consultation, 75.2% disagree for MDR and 77.8% disagree for IVDR.

[85] Call for Evidence – 34 out of 121 respondents: 10 Business, 8 Health Providers, 6 Business Associations, 4 EU Citizens, 3 NGOs, 2 Academics, 1 Public Authority.

[86] Call for Evidence – 28 out of 121 respondents: 12 Business, 8 Business Associations, 3 EU Citizens, 2 NGOs, 2 Non-EU Citizens, 1 Other.

[87] Call for Evidence – 34 out of 121 respondents: 10 Business, 8 Health Providers, 6 Business Associations, 4 EU Citizens, 3 NGOs, 2 Academics, 1 Public Authority.

[88] See note 69, page 15, for other sources confirming this.

To what extent have the Regulations ***increased trust of patients, professionals, and industry*** *in the EU regulatory system?*

In 2017, the Regulations introduced strengthened safety requirements to the EU medical device regulatory framework with expectations to rebuild confidence and address concerns that emerged from safety crises under the Directives[89]. However, today the level of trust in the system remains low. Qualitative evidence shows that despite progress, implementation inconsistencies, limited transparency, and procedural inefficiencies continue to undermine confidence in the system. While there is no pre-Regulation baseline data available to assess how trust has evolved, stakeholder feedback reveals persistent uncertainty and scepticism.

Although no major safety crises have occurred since the introduction of the Regulations, confidence in the system varies widely. Public consultation responses show that less than 20% of participants believe that the Regulations significantly contribute to trust in the regulatory system (economic operators being the most sceptical group, followed by national competent authorities and healthcare professionals[90]). Other findings from the governance study survey echo those differences: 71% of consultants and notified bodies perceive an increase in trust, while only 46% of economic operators and trade associations share this view[91]. Qualitative evidence reinforces these trends, describing a lack of trust linked to regulatory complexity, inefficiencies in the way the system operates, uneven application across Member States, and divergences in interpretation[92].

18 out of 87 respondents to the Call for Evidence link trust to greater transparency, safety, and accountability, suggesting that while trust is low, it can be rebuilt through clearer, harmonised, and evidence-based regulation[93]. One healthcare provider explained that a transparent regulatory system is central to building trust in the use of devices, giving the example of the need for publicly shared and easily accessible clinical evidence[94]. Whilst not yet achieved, the level of trust in the system could increase once the Regulations are fully implemented and are interpreted and applied in a consistent manner, with improved device transparency and more operational efficiency.

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[89] Notably safety of Poly Implant Prothèse (PIP) Silicone Breast Implants, Metal-on-Metal joint replacements, and surgical meshes used in urogynaecological surgery.

[90] Public consultation (answers to the PC are not statistically representative of the EU population, as respondents with negative perceptions might have a higher participation rate). Economic operators: around 60% (MD) and 65% (IVD) disagree that the Regulations have strengthen trust, while for healthcare professionals: 58% for MDs and 77% for IVDs share this view.

[91] Ernst and Young, *Study on Regulatory Governance and Innovation in the field of Medical Devices - Final report*, Publications Office of the European Union, 2025, DOI:10.2875/8995410. Hereafter 'study on governance'.

[92] Call for Evidence – 87 respondents: 27 Company/Businesses, 16 EU citizens, 13 Health Providers, 9 Business Associations, 6 other, 4 non-EU Citizen, 3 NGOs, 3 Academic/Research Institutions, 2 Consumer Organisations, 2 Patient Organisations, 1 Public Authority and 1 Notified Body. Questions 5.50 and 6.50 in Public consultation: "*What do you see as the most important barrier to building trust in the regulatory system of medical devices in the EU*?". For MDR, more than 85% respondents and the IVDR approximately 80% shared these concerns.

[93] Call for Evidence – 18 out of 87 respondents: 6 from Health Providers, 5 from Company/Business, 4 from Business Associations, 2 from NGOs, 1 from Public Authority.

[94] Call for Evidence.

4.1.1.2. Notified bodies, conformity assessment procedures and clinical evidence

The Regulations are based on the New Legislative Framework[95], which relies on the conformity assessment of products. For medium and high-risk devices, the involvement of a notified body in the conformity assessment is mandatory before CE-marking and thus allowing the placing on the market. Given the fundamental healthcare role of medical devices and IVDs, the Regulations sought not only to ensure the smooth functioning of the internal market, but also to increase patient safety by enhancing the pre-market requirements for devices, including the generation of clinical evidence. Thus, in 2017 the Regulations were expected to ensure a consistent and effective designation and oversight of notified bodies across the EU, streamline conformity assessment procedures, and strengthen clinical evidence requirements. Overall, the notified body designation and oversight remain uneven, conformity assessment processes are perceived as unpredictable and inefficient (see negative score in *Annex VI, Table 2*). Whilst notified body capacity was initially insufficient under the Regulations, MDR-designated notified bodies have now reached a comparable capacity to under the Directives, whilst for IVDR, it remains to be determined. Although a level fragmentation can be expected in a decentralised certification system, the increased harmonisation in conformity assessment activities by notified bodies sought under the Regulations has not yet been achieved, partially due to divergent interpretation of requirements and oversight capacity of notified bodies by authorities. Finally, clinical evidence requirements have been enhanced[96] (though stakeholders question their proportionality for low and medium risk devices, *see section 4.1.2*). However, judging the quality and availability of clinical evidence and the correlation to improving device safety remains challenging due to the on-going implementation of the Regulations.

*To what extent are **notified bodies designated and overseen effectively** and consistently across the EU?*

In the first years of application of the Regulations, the number of designated notified bodies was insufficient to respond to certification demand for both legacy devices (transitioning from the Directives to the Regulations) and new technologies. This bottleneck can be partially explained by the initial **long designation timelines**, which have however experienced a positive evolution over time. Indeed, whilst designation now averages at 1041 days (median: 1022 days) for MDR and 1166 days (median: 1296 days) for IVDR, this has been decreasing overtime (the latest notified bodies to apply and achieve designation took 745 days for MDR-designation and 686 days for IVDR-designation)[97] (see *Annex VII, Figures 3 & 4*). In addition, the large variation in the number of days spent across designation milestones shows poor harmonisation of the process. The two longest steps of the designation process are the on-site checks of corrective plans by the notified

[95] Decision No 768/2008/EC, OJ L 218, pp. 82–128, ELI: http://data.europa.eu/eli/dec/2008/768(1)/oj.
[96] Call for evidence, 211 entries referenced requirements for robust clinical evidence.
[97] European Commission, internal sources.

body, which are approved by the authority[98], with a median of 245 days for MDR, 194 days for IVDR, and the Joint Assessment Team's[99] (JAT) delivery of its opinion on the corrective plan to national authority's decision, with a median of 197 days for MDR and 134 days for IVDR (see *Annex VII, Figure 5)*. These two longest steps are entrusted to the designating authority and the notified body, and do not involve the JAT which includes both Commission and national experts.

Moreover, most non-compliances raised during the designation of notified bodies relate to process and resource requirements, affecting designation length, and the number raised varies significantly among Member States. This indicates additional variation in national processes and the difficulty for notified bodies to meet such requirements. In addition, even though the joint assessment process is intended to bring consistency and a harmonised approach to designation, the number of national experts participating in it does not necessarily correlate to the number of notified bodies in a country.

The **number of notified bodies** under the Regulations has increased significantly over time after, an initial delay[100] (see *Annex VII, Figure 6)*. Consequently, stakeholders no longer view notified body capacity as a main problem for medical devices. However, for IVDs, despite the positive evolution in the number of IVDR-designated notified bodies, a greater proportion now require notified body involvement in conformity assessment than under the Directives. Numbers are expected to further increase with 12 MDR and 6 IVDR designation applications on-going[101]. In terms of the **designation scope for notified bodies** (i.e., device types they are authorised to certify[102]), notified bodies have obtained 92% of medical device codes and 97% of IVD codes that they applied for[103]. However, medical device codes are not always evenly spread among notified bodies, with low coverage codes generally concerning highly complex devices requiring specialised expertise (e.g., active implantable medical devices). **Capacity to certify different device types therefore may vary.** Difficulties for notified bodies in obtaining all desired codes, may be linked to stricter resource requirements under the Regulations, where non-compliances are often raised. Whilst scope extension requests are possible after initial designation, (with 3 of 9 requests under the Regulations to date completed), the process is burdensome requiring a repeat of the whole designation process to achieve the extension.

National designating authorities independently perform **notified body oversight**, through on-site audits, review of personnel files and technical file assessment without any direct

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[98] On-site assessment of Corrective and Preventative Action (CAPA).

[99] Joint Assessment Team (JAT) as described in Article 39(3) MDR and Article 35(3) IVDR.

[100] European Commission website on the New Approach Notified and Designated Organisations (NANDO) Information System: see the list of MDR and IVDR designated notified bodies: As of October 2025, 51 MDR-designated notified bodies (6 of which that were not designated under the Directives) and 19 IVDR-designated notified bodies (2 of which that were not designated under the Directives) were registered in the NANDO Information System.

[101] European Commission website, *Overview of CABs/NBs at each stage of the designation process*.

[102] See list of codes and corresponding types of devices for the purpose of specifying the scope of the designation as notified bodies (Commission Implementing Regulation (EU) 2017/2185, OJ L 309, 24.11.2017, pp. 7–17) and Coverage of designation codes by MDR/IVDR notified bodies (European Commission website, June 2025).

[103] European Commission, internal sources.

central oversight. Coordination takes place at EU level through the MDCG, the subgroup for notified body oversight (NBO[104], with 21 meetings, 29 MDCG-endorsed documents[105]), the Notified Body Coordination Group (NBCG-Med, with 12 meetings, 3 documents) and via information sharing (national designating authority annual reports). Despite growing national monitoring activities and EU coordination efforts, the level of coordination of notified body oversight remains insufficient. Stakeholders often cite differences in interpretation and application of notified body requirements as a source of fragmentation and unpredictability in the system[106].This is due to varying procedures by different designating authorities, leading to diverse monitoring outcomes and ultimately, a lack of harmony in the activities of notified bodies across the Union.

*To what extent are **conformity assessments carried out effectively**, predictably and consistently?*

Whilst the number of designated notified bodies and **full-time equivalent (FTE)** staff have increased, insufficient data on certification demand makes it difficult to determine whether resources are sufficient and used efficiently. Over 1 500 FTEs (>30%) are dedicated to administrative and supporting tasks, which are not related to core conformity assessment activities[107]. The issuance of a new certificate takes 6-18 months (Quality management system (QMS) only) and 13-24 months (QMS and product) in most cases, and **certification time** is almost evenly attributable between the manufacturer and the notified body.[108] In terms of application processing, notified bodies often cite poor application quality and manufacturer preparedness as reasons for refusals. The vast majority of refusal of applications was due to *'outside scope of notified body's designation'* (631/1,149 or 54.9%), followed by *'application not complete'* (179/1,149 or 15.6%) and *'wrong qualification of product/classification of device'* (148/1,149 or 12.9%)[109]. Finally, of notified bodies using structured dialogue[110] (i.e., exchanges of technical and regulatory information between the notified body and manufacturer to facilitate the application process), 75.7% estimated less than a 25% reduction or no reduction in the length of the conformity assessment. Conversely, early dialogue is often cited by stakeholders as a key tool for planning and developing clinical investigations[111].

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[104] See *Terms of reference of the MDCG Working Group, Notified Bodies Oversight (NBO)*, 2018.

[105] European Commission website, 29 *MDCG-endorsed documents on Notified Bodies* and 3 , *NBCG-Med documents*.

[106] Position papers, Call for Evidence.

[107] European Commission website – *Study supporting the monitoring of availability of medical devices on the EU market*. *The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH/GÖG), in collaboration with Areté and Civic Consulting*, 12th Notified Body survey, questions for the Targeted Evaluation. Hereafter 'Notified body survey'.

[108] See note 107, page 21; also reported in Economic operator survey.

[109] Economic operator survey.

[110] MDCG, *Questions and answers: Requirements relating to notified bodies Revision 5*, MDCG 2019-6 Rev5, February 2025.

[111] European Commission: Directorate-General for Research and Innovation, Cavicchi, B., Florindi, F., Gilbert, S. and Vuorinen, H., *EU R&I policy as an enabler of MedTech innovation – Addressing development and market integration challenges*, Publication Office of the European Union 2025 **https://data.europa.eu/doi/10.2777/4917399**.

There has been a negative evolution in the perceptions among economic operators on the level of harmonisation of notified bodies' conformity assessment activities[112], with respondents more likely to disagree that they are more harmonised under the Regulations than the Directives. One example of this issue is the inconsistency in how notified body fees are presented. Although all notified bodies make their fees publicly available[113], most do not adhere to the template list of standard fees established by the MDCG, which hampers the formation of a level playing field across Member States.

*To what extent have requirements for **clinical evidence** improved device safety and performance?*

The number of **clinical investigation** applications has remained steady throughout the years, with the proportion of granted (~85%) versus denied (~15%) also remaining stable[114], with however, significant variation in the number received per country. Stakeholders have raised this and called for a central structure for coordination of multi-national clinical investigations, and enhanced transparency and accountability[115]. In addition, the number of clinical investigations for research purposes, post-market clinical follow-ups (PMCFs) and performance studies have all increased[116]. This demonstrates that pre-market research & development continues to take place, and an increasing level and quality of clinical data may support the making available of new devices.

Moreover, to support the generation of quality clinical data, new **structures for scientific oversight** have been established and their use is steadily increasing every year, with 77 Clinical[117] and Performance procedure[118] submissions to expert panels in 2024 alone and 31 opinions issued since their inception. However, stakeholders have highlighted that these consultation procedures alone are not sufficient for developers. Indeed, early dialogue with regulators and notified bodies, and the possibility to get clear guidance at an early stage (i.e., regulatory advice) are often cited as potential approaches that would allow developers to shape their clinical investigations and evidence generation strategies more effectively to meet regulatory requirements[119,120], particularly for highly innovative medical devices and IVDs. The notion that developers struggle with preparing regulatory documentation, is supported by the notified body survey, where 71.2% of respondents reported over 50% of clinical evaluation reports (CERs)/ performance evaluation reports (PERs) they receive are incomplete or inaccurate, and 52.5% indicated over 75% are incomplete or inaccurate.

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[112] Public consultation, call for evidence, position papers, and reality check workshop.
[113] European Commission, *Published fees on notified bodies websites for MDR and IVDR related services*'.
[114] Targeted national competent authority survey.
[115] Workshop with MDCG stakeholders on 03 April 2025
[116] Targeted national competent authority survey.
[117] Clinical Evaluation Consultation Procedure (CECP), Article 54 MDR - https://health.ec.europa.eu/medical-devices-expert-panels/experts/list-opinions-provided-under-cecp_en.
[118] Performance Evaluation Consultation Procedure (PECP), Article 48(6) IVDR - https://health.ec.europa.eu/medical-devices-expert-panels/experts/list-views-provided-and-ongoing-consultations-under-pecp_en.
[119] Reality check workshop with manufacturers.
[120] See note 111, page 21.

Furthermore, in terms of access to clinical evidence, most clinical investigation and performance study reports and their summaries (SS(C)Ps) are not made public (see *section 4.1.1.1*). Consequently, healthcare professionals, patients and users' perceptions are that clinical evidence may be increasing, but its availability and their access to it remains low, thus hampering patients and users' ability to make informed decisions on devices.

4.1.1.3. Market functioning and level playing field

The availability of devices, fair competition, and global competitiveness of the EU industry are essential for market functioning and ensuring patients' access to devices that meet their needs. In 2017 when the Regulations were adopted, they were expected to enhance competitiveness, foster innovation, and as a result, maintain broad device availability across the EU. To date, these objectives have been only partially achieved: while the regulatory framework has increased oversight and safety of devices, its complexity and uncertainty have constrained innovation and competitiveness, particularly for SMEs (see negative score in *Annex VI, Table 3*). This has resulted in longer timelines and limited device availability, notably affecting niche and orphan devices where limited profitability and high compliance burdens have led to portfolio reductions and market withdrawals.

To what extent have the Regulations affected ***competitiveness and innovation*** *of EU industry?*

The European **market** of medical devices is estimated at 170 bn EUR in 2024, making it the second largest after the United States (US)[121]. The European medical device sector has demonstrated steady growth since 2017, with an average of 6% per year for medical devices and 4.3% for IVDs over the past decade, measured in terms of manufacturer prices[122]. This expansion, however, does not necessarily mean a proportional increase in innovation and competitiveness. Instead, it likely reflects broader market expansion and rising demand.

The EU remains the second leading originator of **patents** worldwide in the medical devices sector, following the US[123]. Patents granted increased by 29.5% between 2017 and 2024 and the number of patent applications increased by 19% over the same period, showing a slight increase in the overall patents approved[124]. The steady patenting performance, together with the EU's strong **export** position[125], indicate a continued capacity for innovation, commercial attractiveness and research and development investment[126]. However, evidence of this on the market is not yet apparent.

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[121] MedTech Europe website, *Facts and Figures 2025* (see footnote 3 page 2).
[122] See note 121, page 23.
[123] European Patent Office, *Patent Index 2024*.
[124] See note 121, page 23.
[125] Europe had a medical devices trade balance of 5 billion EUR in 2024, with its main trade partners being the US, China, Japan, and Mexico. See note 121, page 23.
[126] Europe's strong incentives, skilled talent pool and growing support for entrepreneurship make it an attractive environment for medtech innovation and R&D investment, based on MedTech Europe - *Europe's Attractiveness for Innovation, State of Play and Recommendations*.

In the **international setting,** the EU's bilateral and multilateral activities have continued under the Regulations. The EU has strengthened its role in the International Medical Device Regulators Forum (IMDRF)[127], with the European Commission and 8 Member States being involved in all working groups[128] and continued implementation of IMDRF guidance[129]. While the number of bilateral operational agreements has declined since 2017, progress includes updates to the EU – Turkey Custom Union for medical devices[130]. Despite continued reliance on EU MDR/IVDR certificates by other jurisdictions (125 for medical devices, 45 for IVDs[131]), implementation challenges have reduced their exclusive use, with new reliance frameworks emerging. The EU's observer role in the Medical Device Single Audit Program (MDSAP)[132] – where 13 EU designated notified bodies also act as Auditing Organisations and over 1 600 MDR and IVDR certificates have been issued through combined audits[133] – illustrates its ongoing engagement. Should the EU decide to take a more prominent role in MDSAP, this would allow further convergence, process simplification and international competitiveness.

Stakeholders express caution about the Regulation's impact on **innovation**. In the public consultation a large majority of stakeholders strongly disagreed that the Regulations contributed to innovation[134]. In the governance study survey, 60% of stakeholders indicated that MDR does not stimulate the introduction of highly innovative devices on the EU market, while 48% share this view for IVDR[135]. Such perceptions are particularly critical for SMEs and start-ups, which often face higher relative compliance costs and limited resources to navigate lengthy conformity assessment processes. Innovation and first market entry are increasingly shifting to other regions, particularly the US where regulatory pathways are seen as more predictable, faster, and less costly for SMEs[136]. While the EU market remains large and resilient, the regulatory framework is perceived as a significant barrier to enhanced innovation and competitiveness. Stakeholders point to the need for specialised regulatory pathways for innovative devices to ensure their availability[137] and highlight the need to develop structured, harmonised early scientific and regulatory dialogue frameworks.[138]

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[127] IMDRF website, https://www.imdrf.org/.
[128] IMDRF, *Working Groups* 3 working groups are led by a representative of the EU or of an EU Member States.
[129] IMDRF Management Committee, *IMDRF Document Implementation Report*, IMDRF/MC/N84 FINAL:2025 (Edition 2), 1 September 2025.
[130] See note 9, page 3.
[131] Public Consultation: number of other jurisdictions relying on EU CE marking for MD and IVD.
[132] MDSAP global, *Auditing Organisations*.
[133] See note 107, pg 21.
[134] Public consultation: MD: 86.6% disagreed and strongly disagreed; IVD: 85.8% disagreed and strongly disagreed.
[135] Study on governance.
[136] Call for Evidence, Study on governance, Position Papers.
[137] Study on governance '"[…] when it comes to specific initiatives for fostering innovation, stakeholders often pointed to the need for specific regulatory pathways for innovative devices, taking inspiration from for example the 'Breakthrough Devices Program'.
[138] See note 111, page 21, stakeholder recommendations for 'Centres for Excellence in Regulatory Science and Innovation'.

*To what extent have the Regulations ensured a **level playing field for economic** operators across the EU?*

The Regulations have introduced a strengthened and single EU regulatory framework for ensuring device safety and performance, yet discrepancies in the application of requirements across notified bodies and Member States have led to uneven compliance practices, affecting costs and timelines and disproportionately impacting SMEs. A majority of consulted stakeholders[139] stated that inconsistencies in the interpretation, implementation, and costs of the Regulations across Member States and notified bodies create an uneven playing field. In the conformity assessment process, fragmented practices notably by notified bodies and designating authorities (see *section 4.1.1.2*) have led to a lack of predictability of the processes and have hampered the Regulations' objective to ensure an even playing field. To address these challenges and restore confidence in the regulatory framework, stakeholders call for greater EU-level harmonisation of application of requirements, reduction of costs, and cost-efficiency of procedures[140]. Healthcare professionals, insurers, and EU bodies advocate for more centralised processes and fees[141].

*To what extent have the Regulations affected the **availability of devices** on the EU market (shortages, withdrawals, delays)?*

Although it would have been expected in 2017, similar to under the Directives, comprehensively determining the **number of medical devices** available on the EU market is not yet possible. For this, full implementation of UDI and complete registration requirements in EUDAMED are needed. For the number of devices, the lack of reliable baseline data makes it challenging to estimate the portion of devices that may not transition to the Regulations, or that if discontinued, would be deemed unacceptable. Moreover, device availability is also influenced by broader economic factors, such as supply chain disruptions and demand fluctuations. It is therefore not possible at this stage to credibly estimate the extent to which the Regulations alone have affected device availability.

The number of **applications lodged** by manufacturers **and certificates issued** under the Regulations is however monitored. Data collected between February 2021 and October 2024 shows that the number of applications and certificates has steadily increased[142] (applications filed under MDR: 28 069 and IVDR: 2 201; certificates issued under MDR: 10 554 and IVDR: 1 273), with the number of certificates issued begin comparable to that under the Directives[143]. Transition progress remains uneven as 14/50 notified bodies stated

[139] Call for Evidence – 112 out of 176 respondents: 48 from Company/Business, 22 from Business Association, 15 from Health Provider, 10 from EU Citizen, 6 from Other, 5 from Academic/Research Institution, 3 from NGO, 2 from Public Authority, 1 from Trade Union.
[140] Call for Evidence, Position papers.
[141] Call for Evidence, Position papers.
[142] See note 107, pg 21. Surveys conducted from February 2021 – October 2024.
[143] This is compared to 25,034 MD/AIMD and 1,551 IVD certificates issued under the Directives.

that fewer than a quarter of their clients have completed the MDR-certification for all intended devices and an equal share indicated completion rates above 75%[144].

Recent evidence shows that so far, few notifications on **interruptions or discontinuations in device supply** with a patient or public health risk[145] have been made under the prior notification obligation for manufacturers (Article 10a) applicable since January 2025[146]. Whilst Article10a is facilitating oversight for authorities on the root causes of supply issues, improving information to the downward supply chain and shortage management in non-crisis situations, predicting potential shortages and their impact on healthcare systems remains difficult. Enhancing synergies with existing monitoring systems, such as the EMA's reinforced role in crises preparedness and management of medical devices[147], could further improve governance in the emerging area of medical device shortage management.

As for **stakeholder perceptions on availability and potential shortages**, they vary considerably. Manufacturers are most likely to raise concerns on reduced availability[148], with recurring reasons[149] for discontinuing certain devices including "revenue not justifying approval", "products with low sales volumes", "low profitability", or "products at end-of-life cycle"[150]. At the same time, healthcare professionals broadly confirm difficulties in maintaining supply: almost 60% have faced shortages in the past 3 years, and 61% of European hospital pharmacists report shortages in their hospitals[151]. Although citizens are least likely to indicate problems[152], it was underlined that shortages have adverse consequences for patient care, with disproportionate effects on vulnerable groups such as children, patients with rare diseases, and those requiring non-standard sized implants[153]. Overall, despite recognising the Regulations' stricter requirements, stakeholders critique inefficiencies, delays, and lengthy procedures resulting in disproportionately high costs particularly for SMEs, orphan devices, and low-risk products[154], thus impacting market availability.

In this context, and especially for **orphan devices** which are critical for patients with limited treatment alternatives**,** stakeholders consistently highlight the risk of

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[144] See note 107, pg 21.
[145] Since January 2025: approximately one third of 40 notifications received concern devices with no alternatives.
[146] European Commission, *The information obligation in case of interruption or discontinuation of supply of certain medical devices and in vitro diagnostic medical devices*, Q&A, Rev 1, December 2024.
[147] Regulation (EU) 2022/123, OJ L 20, 31.1.2022, pp. 1–37, ELI: http://data.europa.eu/eli/reg/2022/123/oj.
[148] Call for Evidence – 393 responses highlighted reduced availability under the MDR/IVDR: 139 company/businesses, 76 health providers, 62 EU citizens, 40 business associations, 22 other, 18 academic/research institutions, 9 NGOs, 8 non-EU citizens, 7 public authorities, 5 patient organisations, 3 consumer organisations, 2 trade union, and 2 notified bodies.
[149] Economic operator survey.
[150] Economic operator survey.
[151] Position paper. This is also confirmed in the *Study supporting the monitoring of availability of medical devices on the EU market. The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH/GÖG), in collaboration with Areté and Civic Consulting*, Survey on the Health Service Providers.
[152] Public consultation: 15 out of 16 EU citizens indicated that in the past 3 years they did not have issues with the availability of devices they wanted to or should use.
[153] Study on governance, Position papers, Economic operator survey.
[154] Position papers.

discontinuations (see *Annex V*), with over half of manufacturers having planned portfolio reductions[155]. In 2024 only 52% of manufacturers intended to transfer their orphan devices to the MDR, while 29% planned none, and 26% would transfer less than 5% of IVDs[156]. These findings align with broader stakeholder perceptions. A majority indicated in the governance study survey that the Regulations contribute little or not at all to the availability of niche or orphan devices, with national competent authorities, health institutions, and patient organisations being especially critical[157]. Overall, 132 out of 393 stakeholders reported disproportionate impacts on SMEs and niche products[158], confirming market pressures and compliance costs continue to threaten the availability of orphan devices[159]. To address this challenge, in addition to clarifications in an MDCG guidance[160] and an orphan device support grant[161], the EMA has launched a pilot programme to support the development and assessment of orphan medical devices[162]. Stakeholders underline however the gap in dedicated regulatory pathways[163] in order to secure a sustainable supply of orphan devices, which could be further explored.

To what extent do the Regulations address ***specific needs of patients and users*** *(e.g. rare diseases, paediatrics, accessibility)?*

Though not expected in 2017, the implementation of the Regulations has created challenges regarding the availability of devices for patients with specific needs that prevent the objective of ensuring a high-level of protection of patient health and safety from being fully achieved in practice. For example, the Regulations introduced minimum conditions to regulate **in-house devices** manufactured and used within health institutions (as compared to the Directives), however their implementation has proven challenging. A majority of consulted stakeholders explicitly highlight documentation, validation, and equivalence requirements as overly burdensome[164] and 22 out of 124 stakeholders further flag difficulties in transferring in-house devices. A smaller share call for national-level regulation instead of EU oversight[165]. Due to the high regulatory burden, 75% of such tests were estimated in one evidence source by stakeholders to be discontinued[166]. In-house devices are an important category in the field of IVDs and public health laboratories also stress their importance for crisis preparedness, given in-house devices assay rapid

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[155] MedTech Europe, *MedTech Europe Survey Report analysing the availability of Medical Devices in 2022 in connection to the Medical Device Regulation (MDR) implementation*, 14 July 2022.
[156] MedTech Europe, *MedTech Europe IVDR & MDR Survey Results 2024*, Public Report, December 2024.
[157] Study on governance.
[158] Call for Evidence – 132 out of 393 respondents: 54 from Company/Business; 26 from Health Providers; 20 from EU Citizens; 16 from Business Associations; 8 from Other; 6 from Academic/Research Institutions; 2 from NGOs
[159] Study on governance, Call for Evidence, Position papers.
[160] MDCG, *Clinical evaluation of orphan medical devices*, MDCG 2024-10, June 2024.
[161] EU Funding & Tenders Portal (2023), EU Funding & Tenders Portal (2025).
[162] For further information see the EMA website, *New pilot programme to support orphan medical devices*.
[163] Position papers.
[164] Call for Evidence – 72 out of 124 respondents: 45 from Health Providers, 10 from Company/Business, 7 from Business Associations, 5 from EU Citizens, 3 from Academic/Research Institutions, 1 from Patient Organisations, and 1 from NGOs.
[165] Call for Evidence – 88 out of 275 respondents: 40 from Company/Business, 20 from Business Associations, 10 from Health Providers, 8 from EU Citizens, 5 from NGOs, 3 from Academic/Research Institutions, 2 from Others
[166] Reality check with healthcare professionals, users and patients.

diagnostics respond to novel pathogens or variants. Although data on the number of in-house-devices and health institutions is scarce (due to fragmented national records and no EU-level registration), one large university hospital reported that about half of its IVDs are in-house devices, with 70% having no market alternatives[167] .

To address specific needs, the Regulations also provide for the possibility to grant a **derogation from conformity assessment** for a device under specific circumstances, based on a **patient or public health need**[168]. Since the application of these provisions in 2020 (MDR) and 2022 (IVDR), the national derogation procedure has been frequently used (750 MDR and 49 IVDR derogations granted) but the EU-wide mechanism has only been used once. Whilst this mechanism helps meet patient needs, inefficiencies arise from multiple derogations being granted across Member States for the same device and manufacturer,[169] indicating the number of devices benefitting from derogations is lower than reported. This may indicate the need for an adapted streamlined process, based on scientific evidence (for example, using expert panels), to improve device availability and meet patient needs in situations of urgent health and safety.

In the public consultation, 46% of respondents agreed that the MDR contributed to protecting the health of patients in relation to medical devices (44% for IVDR), while 40% agreed that it contributed to protecting the health of users (35% for IVD)[170] (see *Annex V*). These gains must be weighed against implementation challenges, particularly for SMEs and manufacturers of niche and orphan devices.

4.1.1.4.Post-market surveillance, vigilance and market surveillance

The post-market surveillance, vigilance and market surveillance systems under the Regulations were expected to provide stronger and more coordinated mechanisms for detecting and addressing risks across the EU. To date, these objectives have been largely achieved, with clear progress in coordination among national authorities and improved reporting and oversight, resulting in increased device safety monitoring capacity (see positive score in *Annex VI, Table 4*). However, remaining inefficiencies and resource limitations at both EU and national levels, combined with the on-going implementation of the Regulations, mean that the full potential of the system is not yet realised.

*To what extent has **post-market surveillance and vigilance improved** the detection and management of risks?*

The Regulation's strengthened provisions aim to protect health, patient safety and public health by facilitating the availability of comprehensive safety information and enhancing

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[167] Vermeersch, Pieter., Van Aelst, Tobias and Dequeker, Elisabeth M.C., The new IVD Regulation 2017/746: a case study at a large university hospital laboratory in Belgium demonstrates the need for clarification on the degrees of freedom laboratories have to use lab-developed tests to improve patient care, *Clinical Chemistry and Laboratory Medicine (CCLM)*, vol. 59, no. 1, 2021, pp. 101-106. https://doi.org/10.1515/cclm-2020-0804.

[168] See Articles 59 MDR/54 IVDR. Derogations can be granted at national or in exceptional circumstances, at EU level.

[169] European Commission, internal sources.

[170] Public consultation.

post-market safety coordination. Three interlinked and reinforced systems were established: **(a) post-market surveillance**, where manufacturers continuously monitor devices after market placement **(b) vigilance,** where manufacturers report incidents (which national competent authorities evaluate) and conduct field safety corrective actions; and **(c) market surveillance,** where national competent authorities oversee and control devices on the market. These systems involve all supply chain actors, including manufacturers, importers and distributors, national competent authorities, notified bodies, healthcare professionals, patients and other users of devices. Overall, citizens agree that **devices are sufficiently monitored** (76.5%, 0 disagree), and stakeholders agree that safety issues are adequately identified and addressed (74.1%)[171]. Nevertheless, there is mixed awareness on how to report incidents by healthcare professionals, with only 46.9% agreeing that they are informed on where to report an issue with medical devices, and none agreeing when it comes to IVDs.

With regards to **post-market surveillance and vigilance**, a general increase can be observed in reporting activity by manufacturers. Between 2022 and 2024, medical device serious incident reports (MIR) have increased over 20%, periodic safety reports (PSR) over 30%, and field safety corrective action (FSCA) reports about 1%[172]. Nevertheless, evaluating the effectiveness of the Regulations in ensuring a high level of health protection in the post-market context is complicated by the predominance of devices that were already placed on the market under the previous regulatory framework (legacy devices). Therefore, whilst the increase in reporting reflects an **increased capacity to detect and potentially manage emerging safety risks**, it remains challenging to assess whether any evolution observed reflects changes in device safety or only on reportability. Conversely, most economic operators indicated that the number of MIRs they submit to national competent authorities has not increased under the Regulations compared to the Directives and that no MIRs have led to a FSCA[173]. This discrepancy with the figures provided by national competent authorities may be explained by either a low number of manufacturers providing a significant proportion of the increased numbers of reports, or by potential differences in how reporting numbers are interpreted by manufacturers and authorities.

With regards to **market surveillance** activities by national competent authorities, the number of product samples controlled has seen an over eight-fold increase since the application of the Regulations[174]. In addition, the overall number of exchanges on device compliance between authorities (compliance exchange forms (CEFs) sent), have increased over 25% since the application of the Regulations, which is a positive indication for increased coordination on safety issues on the market. Moreover, for areas where market surveillance activities have not increased, evidence shows that activity has remained steady. For example, the number of proactive and reactive on-site inspections has not

[171] Public consultation.
[172] European Commission, internal sources, targeted national competent authority survey.
[173] Public consultation: only 26/170 or 15.3% indicated that it had increased; only 40/170 or 23.5% indicated that at least one MIR had led to a FSCA.
[174] European Commission, internal sources

changed since the application of the Regulations, with less than a quarter of national inspection reports having a corresponding final inspection report[175]. Experience with market surveillance enforcement measures is beginning, though data so far is limited.

Therefore, whilst under the Directives the obligations and empowerments for national competent authorities on market surveillance were significantly less developed, the above shows a positive increase in device safety monitoring capacity in the system. Owing to the short implementation timeline of the Regulations, it is difficult to judge the effectiveness of the market surveillance system at this stage. Nevertheless, this enhanced device safety monitoring capacity is anticipated to improve the ability to detect and address potential safety issues as they emerge.

Finally, whilst informal cooperation mechanisms existed under the Directives, the Regulations introduced **coordination and cooperation obligations of vigilance and market surveillance activities** by national competent authorities, to ensure a harmonised and high level of safety **enforcement** for devices. These have started to increase. For vigilance, there have been 149 coordination exchanges between national competent authorities. For market surveillance, competent authorities have formed three task forces to address device-specific safety issues and are participating in two joint actions[176,177]. Whilst joint actions are proving a useful tool to improve harmonisation of market surveillance, the evaluation has identified a lack of stable mechanisms to sustain this high level of harmonised surveillance. Notwithstanding this, coordination is expected to improve once the necessary tools are available, with EUDAMED's *Market Surveillance* module scheduled for mandatory use from 28 May 2026 and the *Vigilance and Post-Market Surveillance* module to follow.

4.1.1.5.Simplification and streamlined procedures

Whilst the Regulations were expected to result in simplified administrative processes and a more efficient use of resources through higher levels of harmonisation and coordination at European level, the evaluation reveals shortcomings, particularly with regards to simplification and streamlined procedures (see negative score in *Annex VI, Table 5*). In general, two types of complexity have been observed: (a) complexity that undermines effectiveness e.g., unclear responsibilities, complex coordination mechanisms, unpredictability in decisions; and (b) complexity that undermines efficiency e.g., redundant reporting, duplicated oversight, administrative burden (see *section 4.1.2*). Both types of complexity result in a reduction of effectiveness and efficiency, respectively.

Regulatory structure and coordination: The regulatory governance framework of the Regulations (see *section 3.2*) is defined by two primary characteristics: a multi-tiered system and decentralisation[178]. Intensive coordination has been needed between EU level

[175] European Commission, internal sources and the targeted national competent authority survey.
[176] European Commission website, *EU funding & Tenders Portal*, Joint Actions on Market Surveillance (JAMS) 2.0.
[177] European Commission website, Joint Actions on Compliance of Products in the EU and EFTA countries (JACOP).
[178] European Commission website, *Medical Devices – Sector - Coordination and Governance*.

actors to operationalise the regulatory infrastructure and play their role effectively. As for coordination between the EU level actors and Member States, ineffectiveness has been observed in the MDCG framework, where the high number of technical sub-groups can lead to duplicative discussions or work, resulting in varied outcomes. In addition, sub-group output is agreed by consensus, which has caused delays in delivering requested clarifications on the Regulations for stakeholders. Furthermore, national designating authorities[179] are tasked with notification and oversight of notified bodies.

This complex governance system has resulted in increased staff time, frequent coordination meetings, and duplicated monitoring or reporting at different levels. Only 28% of surveyed healthcare institutions, professionals or patient organisations, and 35% of economic operators or trade associations, agreed that the **regulatory governance structure and the way of working** are clear[180]. Moreover, only 32% of healthcare institutions, professionals or patient organisations, and 34% of economic operators or trade associations, agreed that **collaboration among actors** is good[181]. Furthermore, only 33% of both national competent authorities and economic operators or trade associations, and 36% of healthcare institutions, professionals or patient organisations, agreed that most issues with the governance structure were temporary and were likely to subside within the following 2-3 years[182]. Examples of governance hurdles cited included perceived ineffectiveness in establishing EUDAMED, monitoring device availability, supervision and coordination of safety issues, and the publication of harmonised standards and common specifications, among others.

Predictability and proportionality: the regulatory system's perceived **unpredictability** was cited as a source of concern[183]. First, stakeholders call for increased harmonisation and coordination of practices among national competent authorities, national designating authorities and notified bodies (and between them). Second, as discussed in *sections 4.1.1.1 – 4.1.1.4*, lack of clear notified body processes, feedback and overall certification timelines are cited as sources of unpredictability, with early dialogue often presented as a potential solution[184]. Third, resource-intensive unannounced audits by notified bodies, lengthy timelines for consultation of other regulatory authorities, for example in the case of drug-device combinations (e.g. medicines authorities) or where relevant authorities for substances of human origin and cells and tissues of animal origin, and uncertainty on notified body approval of (significant) changes, are all highlighted as concerns.

Unpredictability is often combined with a perceived sense of **disproportionality** of requirements, particularly for clinical evidence of **low- and medium-risk device**

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[179] European Commission website, *European Database on Medical Devices - National designating authorities*.
[180] Study on governance.
[181] See note 180, page 30.
[182] See note 180, page 30.
[183] Reality check workshop with manufacturers.
[184] Position papers.

manufacturers[185]. Though some devices can be exempt from certain Regulation requirements by achieving well-established technology designation, this list currently contains only 12 technologies[186] and has not been expanded since the Regulation's introduction. In addition, the involvement of notified bodies in the conformity assessment of devices that did not require them in the past, such as class B IVDs was cited[187] as disproportionate compared to the risks of the devices. The Regulations are often perceived as lacking the necessary **flexibility** to provide adapted regulatory pathways for devices of niche or orphan populations,[188] causing health institutions, healthcare professionals and associations to express concerns about their continued availability (see *section 4.1.1.3)*.

Administrative burden: less than 20% of public consultation respondents agreed that administrative compliance costs are acceptable and will decrease after full implementation of the Regulations, regardless of the specific activity and Regulation consulted[189]. Stakeholders often stress **duplication and overlapping of post-market surveillance and vigilance reporting requirements** as sources of unnecessary administrative burden for economic operators. This includes duplicated assessment of vigilance reports by notified bodies and national competent authorities. 28 responses to the call for evidence indicated that in their opinion, post-market surveillance requirements were overly burdensome and disproportionate, with recurring themes including critiques of excessive documentation, redundant reporting, and disproportionate requirements for low-risk devices or well-established technologies[190]. Additionally, one fourth of public consultation respondents (namely manufacturers) indicated that, upon review, some of the serious incident reports (MIRs) they submitted did not meet the vigilance requirements[191]. Administrative burden can also be observed both in one-time registration of devices and maintenance of economic operator or 'actor' registrations in EUDAMED, along with recurrent reports, such as Periodic Safety Update Reports (PSURs), which are updated either annually or bi-annually depending on device risk-class.

Digitalisation: increasing access to digital technology and the expansion of advanced technologies have revealed some shortcomings with the level of digitalisation allowed by the Regulations. For example, a survey for healthcare professionals on the use of electronic instructions for use (e-IFU)[192] revealed that 88% of respondents prefer e-IFUs compared to the paper version, a solution that has now been implemented[193]. In addition, 61% of respondents agreed that e-IFUs should be expanded to all medical devices, with a further 29% supporting a limited expansion to devices where a healthcare professional trains the

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[185] Call for Evidence – 76 out of 318 respondents: 40 from Company/Business, 15 from Health Providers, 10 from EU Citizens, 6 from Business Associations, 3 from Academic/Research Institutions, 2 from NGOs.
[186] See Article 61(6)(b) MDR.
[187] Call for Evidence.
[188] Call for Evidence, Position Papers.
[189] Public consultation.
[190] Call for evidence.
[191] Public consultation.
[192] European Commission website, *Commission simplifies instructions for use of medical devices to further digitalise healthcare systems*, News Announcement, 25 June 2025.
[193] Commission Implementing Regulation (EU) 2021/2226, OJ L 448, 15.12.2021, pp. 32–38j.

lay user. As a result, the Commission has allowed the use of e-IFUS for all devices intended for professional users and devices without an intended medical purpose[194].

Other potential areas for digitalisation include labelling information not critical to safe device use, using compliance tools to digitally capture information currently contained in multiple documents and reports (such as the EU declaration of conformity), or electronic submission systems for information and documentation related conformity assessment. Furthermore, once UDI and EUDAMED are fully in place, they will enable further digitalisation of device information and help health providers with traceability of devices.

4.1.1.6. Internal and external factors that have contributed to or hindered the progress towards the objectives of the MDR and IVDR

Externally, the COVID-19 pandemic had significant and lasting impacts on the implementation of the Regulations. The pandemic delayed both MDR and IVDR transitions and disrupted audits, performance studies, and laboratory operations under the IVDR. Significant resources were also diverted from the regulatory transition in authorities, to ensure the safe development and availability to EU citizens of essential devices such as COVID-19 tests, and ventilators and masks.[195]

Internal factors relate primarily to the functioning of the governance structure and allocation of resources. The Regulations introduced new coordination systems, notably through the MDCG, which has strengthened cooperation and information sharing between the Member States and the Commission. However, the consensus-based working methods have proven resource-intensive and slow, with lengthy processes for developing guidance documents and achieving harmonised approaches. Overall, while the governance system has improved cooperation, limited resources, complex coordination, and uneven implementation continue to hinder efficiency and the overall progress towards the final objectives of the Regulations.

4.1.2. Efficiency

Annex IV synthesises the efficiency findings under the evaluation, with its *Table 1* summarising the results by stakeholder category as described below. Efficiency is evaluated by assessing the proportionality of resource input to achieved or expected outcomes, rather than by a cost-benefit ratio analysis. This is due to data limitations and the fact the balance between costs and benefits may evolve in the on-going implementation of the Regulations (see further *Annex II, section 3.3*).

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[194] Commission Implementing Regulation (EU) 2025/1234, OJ L, 2025/1234, 26.6.2025.

[195] 11 guidance documents and common specifications were developed for SARS-CoV-2: European Commission website, *Guidance - MDCG endorsed documents and other guidance – COVID-19*.

4.1.2.1.Manufacturers: Costs & Benefits

Costs - Pre-market clinical/ performance evaluation: Manufacturers reported[196] average costs of approximately €30 000–€250 000 per clinical evaluation, depending on device class and study complexity. The range is substantial, with striking differences between certain risk classes: costs for class Ir[197] devices were around €27 700, while class III devices reached as high as €250 000. Performance evaluations under the IVDR also showed wide variation, for example from about €23 000 for Class B to €70 000 for Class C. No costs could be captured on clinical investigations and performance studies, which tend to exceed costs for clinical evaluations. In the consultation process, industry representatives[198] explicitly identified clinical evidence requirements as one of the main cost drivers under the Regulations. Stakeholders highlighted that SMEs and producers of niche devices are disproportionately affected, often lacking the financial and human resources to absorb such burdens[199], with some organisations reporting the need to generate new data has already led to product withdrawals. Some stakeholders also argued that re-evaluation under the Regulations for legacy devices with long proven safety records, is redundant [200] and this would imply additional cost. Finally, as seen in *section 4.1.1.3*, less than half of public consultation respondents were positive on the Regulations contribution to innovation or competitiveness, while many individual comments directly linked negative impacts to the increased costs of clinical investigations and performance studies.

Costs - Conformity assessment: initial certification and maintenance: Certification costs cover both **quality management system (QMS) certificates** (which demonstrate that the manufacturer is operating under a compliant QMS for device production) and **product certificates** (which demonstrate that the relevant device meets the requirements of the Regulations). Data is available on different bases: the economic operator survey interpreted as covering the full compliance burden e.g. technical documentation, clinical data, staff resources etc, in addition to fees charged by notified bodies (reported below as 'costs'); and the interpretation of the notified body survey limited to fees charged (reported below as 'fees'). Data on costs is reported across the **first** (i.e. newly issued) and **last** (i.e. most recent version) **certificates** issued to manufacturers to provide an indication of cost evolution overtime. **Maintenance** costs, which include regular surveillance and re-certification activities, involving assessment of relevant updates to the device(s) covered by the certificate as well as the quality management system, are also reported.

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[196] Economic operator survey.
[197] Class I reusable surgical instruments.
[198] Call for Evidence – 52 out of 211 respondents: 30 from Company/Business, 12 from Business Association, 5 from Health Providers, 3 from EU Citizens, 2 from NGOs.
[199] Call for Evidence – 132 out of 393 respondents: 54 from Company/Business; 26 from Health Providers; 20 from EU Citizens; 16 from Business Associations; 8 from Other; 6 from Academic/Research Institutions; 2 from NGOs.
[200] Call for Evidence – 87 out of 318 respondents: 50 from Company/Business, 15 from Health Providers, 10 from EU Citizens, 7 from Business Associations, 3 from Non-EU Citizens, 2 from Academic/Research Institutions.

For the MDR, **for one type of QMS certificate**[201]**,** reported average issuance costs were 641 878 EUR (25 respondents) for first and 882 988 EUR (56 respondents) and last certificates obtained, a 38% increase, with yearly maintenance costs averaging 73 244 EUR (51 respondents). When considering only the fees charged, costs reached 43 417 EUR for first and 48 968 EUR for last certificates obtained, a 13% increase, with yearly maintenance costs averaging 23 469 EUR. Costs varied by firm size in both sources: large manufacturers paying 165% more than SMEs for the last certificate obtained, which were also higher for large firms in terms of fees. However, data collected did not allow for a comparable analysis of cost proportion between large manufacturers and SMEs, and whether this was explained by device risk or company size.

For **another type of QMS certificate**[202]**,** reported average issuance costs reached 100 000 EUR (1 respondent) for first and 188 524 EUR (7 respondents) for last certificates obtained, with yearly maintenance costs averaging 64 914 EUR (7 respondents). When considering only the fees charged, reported costs were 38 877 EUR for first and 32 954 EUR for last certificates, with yearly maintenance costs averaging 11 674 EUR.

For **certain types of product certificates**[203], issuance costs were of 616 981 EUR (14 respondents) for first certificates and 385 617 EUR (33 respondents) for last certificates, with yearly maintenance costs averaging 48 503 EUR (31 respondents). When considering only the fees charged, reported costs were 75 532 EUR for first and 68 309 EUR for last certificates, with yearly maintenance costs averaging 16 571 EUR. Evidence indicated higher first-certificate costs for high-risk devices (94 109 EUR) than for medium-risk devices (59 262 EUR), while for last certificates medium-risk devices were costlier (77 032 EUR) than high-risk (63 463 EUR).

For **another type of product certificates**[204], overall issuance costs were not available, while fees charged in only two cases suggested issuance costs of 36 657 EUR (first) and 37 932 EUR (last), with zero reported yearly maintenance costs (2 respondents). Similarly, for Annex XI (Part B) only data on fees charged was available (two cases), indicating 7 530 EUR for the last certificate.

For the IVDR, average issuance costs for **QMS Annex IX (I+III)** certificates were reported at 1 205 458 EUR for first (5 respondents) and 388 918 EUR for last certificates (18 respondents), with yearly maintenance costs averaging 121 250 EUR (12 respondents). When excluding one outlier (a 5.5 million EUR multi-device certificate), the average

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[201] QMS certificates under Annex IX (Chapters I+III) cover a full quality management system assessment, including both design and production phases, ensuring MDR/IVDR compliance through the device lifecycle.

[202] QMS certificates under Annex XI (Part A) verify that a manufacturer's quality management system meets the MDR requirements for production quality assurance and ongoing relevant compliance checks.

[203] Product certificates under Annex IX (Chapter II) are issued following an assessment of the technical documentation for a device to verify their conformity with MDR/IVDR requirements.

[204] Product certificates under Annex X are issued after a type-examination procedure confirming that a representative device sample, it's technical documentation and the relevant life-cycle processes meet the relevant safety and performance requirements under the MDR/IVDR.

issuance cost would be 131 823 EUR. For product certificates under **Annex IX (II),** the average issuance costs were 89 750 EUR for first (8 respondents) and 109 700 EUR for last certificates (10 respondents), with change-management costs averaging 13 563 EUR (8 respondents). Only a small number of manufacturers had completed IVDR recertification by late 2024, providing limited data on actual costs (7 respondents). These ranged between 54 000 EUR and 88 000 EUR but are not representative. A larger group of respondents to the economic operator survey provided estimated figures, suggesting total recertification costs of around 143 000 EUR for QMS and 164 000 EUR for product certificates. Taken together, these figures provide complementary perspectives on the cost impacts of certification under the Regulations.

Hassle costs - Waiting times: as seen in *section 4.1.1.2*, notified body capacity shortages were a frequently reported problem across stakeholders in the first years of implementing the Regulations. This shortage created **delays in certification processes** and bottlenecks in market access which was further compounded by lags in the notified body designation process (hence the need for extended transition provisions - see *section 3.2)*. 112 out of 275 contributions to the Call for evidence (40.7%) explicitly highlighted notified body capacity limits and long delays as main obstacles under the Regulations, and variability in notified body practices and costs as a concern[205]. These inconsistencies contribute to unpredictability and longer waiting times for manufacturers. In addition, large manufacturers indicated changing notified body impacted waiting times and resource use, especially those with global market portfolios.

Hassle costs - Administrative burden: Stakeholders consistently flag **EUDAMED-related tasks** as an administrative burden in qualitative inputs[206], showing widespread concern about future transparency- and registration-related obligations once all modules are mandatory to use. No consolidated monetary figure can be reported from these sources in spite of all the consultation efforts. In the call for evidence, several contributions reported significant administrative work for UDI/EUDAMED registration, including IT adaptation, translation of data, and staff time. Smaller operators highlighted the disproportionate burden of setting up data flows for EUDAMED relative to their size and portfolio. However, a large majority of contributions recognised significant advantages once EUDAMED is fully operational. Given EUDAMED is not yet fully deployed or mandatory, some manufacturers must also register in national databases, which is perceived as duplication[207] particularly affecting SMEs. Whilst no harmonised cost figures exist, consultation findings[208] suggest the administrative time for this equals several FTE

[205] Call for evidence – 112 out of 275 respondents: 50 from Company/Business, 20 from Health Providers, 15 from Business Associations, 10 from EU Citizens, 7 from NGOs, 5 from non-EU Citizens, 3 from Others, 2 from Academic/Research Institutions.
[206] Economic operator survey, Call for Evidence, the Public Consultation.
[207] Economic operator survey and Call for Evidence.
[208] Reality check workshop with manufacturers.

days annually. Another source of administrative burden lies in the many and sometimes overlapping **reporting obligations**[209] (see also *section 4.1.1.5*.).

Benefits: Several benefits for manufacturers can be identified based on qualitative evidence. Stakeholders recognise that, in the longer term, the Regulations are designed to provide greater **predictability and legal certainty** by replacing fragmented national systems with a single harmonised EU framework[210]. Opinions are however mixed: while 446 out of 575 respondents mentioned persistent ambiguity and inconsistent application, a minority of respondents noted that the Regulations have the potential to reduce legal uncertainty once implementation stabilises. In particular, some industry associations underline that harmonised guidance and common EU procedures (such as the Helsinki procedure) could over time improve consistency and predictability[211]. Manufacturers also benefit indirectly from stronger requirements for clinical evidence, post-market surveillance, and vigilance which aim to **improve product and therefore patient safety**. Although often described as costly, stakeholders[212] acknowledged that these measures improve the **credibility of CE-marked devices** and **reduce reputational and liability risks**. Higher safety assurance under the Regulations is also recognised[213] as enhancing international trust in EU-manufactured devices. Several contributors pointed out that international reliance mechanisms and **recognition** of CE marking—where applied—can facilitate market access and reduce duplicative assessments, meaning that stronger EU oversight can indirectly improve the **global competitiveness** of compliant manufacturers.

4.1.2.2. Importers/distributors: Costs

Despite consultation efforts, only limited data is available on costs for importers and distributors[214], and none was available on benefits. **Importers** reported an average yearly compliance cost of 115 646 EUR with their obligations (Article 13 MDR/IVDR, verification checks of devices compliance with MDR/IVDR). Excluding an outlier of 5m EUR, the average falls to 32 860 EUR, with 12 importers reporting zero additional costs. For **distributors**, the average yearly cost reported to comply with their obligations (Article 14 MDR/IVDR, verification checks of devices compliance with MDR/IVDR) was 48 615 EUR. Excluding one outlier of 1.5m EUR, the average is 33 496 EUR, with 24 distributors indicating no additional costs.

4.1.2.3. Notified bodies: Costs & Benefits

Costs - Compliance: Notified bodies have faced significant costs linked to their designation and the joint assessment procedures, which are more resource-intensive than

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[209] These include the CEP, CER, PMCF Plan, PMCF Evaluation Report, PMS Plan, PMS Report, PSUR and PSR, SS(C)P, and Trend Reports. See *sections 4.1.1.2* and *4.1.1.4* for acronym explanation.
[210] Call for Evidence.
[211] Position papers.
[212] Call for Evidence.
[213] Position papers.
[214] Economic operator survey.

under the Directives. The need for extensive documentation, repeat rounds of questions, and coordination with multiple national designating authorities has required considerable time investment and additional staff resources. Costs are also driven by staff expansion (particularly experts in clinical, performance, and software assessment), training of staff in the new requirements, and the setup of IT systems for EUDAMED reporting. Capacity constraints meant that notified bodies had to scale up quickly, leading to recruitment challenges and higher overheads. In terms of direct costs, from data collected, it was not possible to determine whether fees charged by notified body covered these.

Hassle costs - Waiting times: The **designation** of notified bodies under the Regulations has been **lengthy and resource-intensive**, (with median timelines of around 1 000 days for MDR and 1 300 days for IVDR, see *Annex VII, Figure 3*) with the longest stages occurring between notified bodies and national designating authorities, pointing to national-level rather than EU-level inefficiencies (see s*ection 4.1.1.2* and *Annex VII, Figure 5*). Stakeholders, including notified bodies themselves, criticise the lack of harmonisation: designating authorities apply different interpretations and requirements, leading to inconsistent designation timelines across Member States. These uneven and protracted procedures create uncertainty and unequal costs for notified bodies. These waiting times delay market capacity, meaning potential lost revenue opportunities for notified bodies from new certificates (when not yet designated under the Regulations), however with income still being generated from their monitoring activities under the Directives and transitional provisions to support administrative and compliance costs.

Benefits: The Regulations have also resulted in increased revenues for notified bodies, as fees charged to manufacturers for certificate issuance and maintenance are reported, based on implementation experience, to have risen significantly compared to the Directives. This benefit is essentially the inverse of the higher costs faced by manufacturers. Several position papers noted that certification under the Regulations has become a core revenue stream for notified bodies, albeit at the cost of higher pressure and scrutiny (see compliance costs of the manufacturers, *section 4.1.2.2)*.

4.1.2.4. National Competent Authorities: Costs & Benefits

Costs: national competent authorities (NCAs) reported a strong increase in human resource needs to manage new tasks: qualification/classification disputes, more complex clinical investigation/performance study assessments, and reinforced vigilance and market surveillance obligations. The establishment of EUDAMED required parallel investment in IT infrastructure and training. Coordination efforts also rose, as NCAs had to participate more intensively in the MDCG structures, in joint assessments of notified bodies, and in the development of guidance. Smaller NCAs stressed disproportionate strain on their budgets and staff.

The significant additional human resources needed to fulfil their tasks were most visible in: the assessment of **clinical investigation (MDR)** and **performance study (IVDR)** applications, with some countries reporting *hundreds* of applications over 2021–2024,

each requiring staff time ranging from **37 to 156 hours** per application[215]; **vigilance and market surveillance**, including trend analysis, follow-up of incident reports, signal detection, and EU-level reporting obligations. These activities represent a significant proportion of recurring cost and resources, even where incident volumes are moderate. In addition, **notified body designation and oversight** by national designating authorities; **regulatory and policy tasks,** including national guidance and policy development, legal issues and qualification/classification disputes required additional resources. On the latter workload varied amongst Member States due to differing number of disputes reported.

Benefits: At the same time, NCAs gained a more central role in harmonised oversight of the market. The framework clarified their responsibilities in vigilance and market surveillance, giving them more legal certainty and a stronger mandate to intervene. The coordinated work in MDCG was also perceived as improving consistency across Member States, though uneven implementation still remains. Overall, NCAs now have stronger tools for market surveillance and can rely on common EU platforms for coordination, device traceability systems for safety monitoring such as UDI and eventually tools, such as EUDAMED once fully deployed and mandatory.

4.1.2.5. Health Providers: Costs & Benefits

Costs: Health institutions experienced **administrative burdens** under the Regulations. Those producing in-house devices, reported extensive documentation requirements without proportional perceived benefits in patient safety. Due to the limited response rate however, there is no significant quantitative information available. Laboratories under IVDR highlighted significant **compliance costs** for validation and performance studies of in-house diagnostics, which diverted resources from research and patient care. Academics, businesses, and health professionals reported **delays in access to innovative devices**, as shortages and market withdrawals affected treatment options, especially in niche therapeutic areas[216]. From one evidence source, a price increase for some medical devices was also reported by health professionals[217].

Benefits: Despite the costs, health providers recognised improvements in **safety assurance** and **clinical evidence** requirements for devices used in their practice. They also welcomed **greater transparency**, particularly through EUDAMED (once fully implemented), which is expected to help them verify compliance and device status.

4.1.2.6. Patients and Users: Costs & Benefits

Costs: For patients, the main costs are **indirect**: reduced availability of devices due to withdrawals from the Union market and delays in certification of innovative products. Patient organisations also highlighted inequities in device availability for rare diseases, paediatric conditions, and vulnerable groups including withdrawals (see *section 4.1.1.3).*

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[215] Targeted national competent authority survey.
[216] Call for Evidence.
[217] Reality check workshop with healthcare professionals, users and patients.

This was echoed in 14% of position papers, underscoring the tension between maintaining high safety standards and ensuring continued access for vulnerable patient populations. In the Call for Evidence, stakeholders noted that extensive and long-term performance study requirements can be difficult to meet for rare conditions, where patient cohorts are small, Patient representatives and users also reported difficulties in signalling device safety issues.[218]

Benefits: Across consultation sources, perceptions of safety outcomes are mixed. Stakeholders generally recognised that the MDR and IVDR have strengthened the regulatory framework by introducing **stricter requirements for clinical and performance evidence**, reinforcing post-market surveillance, and **improving traceability** through mechanisms such as the UDI. Patient organisations and consumer groups also welcomed the increased transparency of CE marking, with EUDAMED expected **to further enhance public access to safety and performance information.**

At the same time, many respondents underlined that these benefits are **not yet fully visible in practice**, mainly because of the gradual implementation and ongoing transition. In the Call for Evidence, 89 out of 253 respondents reported that the Regulations had not yet improved safety for patients—though this reflects perceived delays rather than a decline in safety. The evaluation also confirms that these strengthened safety provisions correspond closely to the objectives identified in the 2012 Impact Assessment, which anticipated that the new framework would prevent major safety incidents, such as those involving defective implants. Although quantitative estimates of avoided incidents or related costs are unavailable, implementation experience indicates no major crises under the Regulations. The Regulations' safety requirements intend to reduce the likelihood and consequences of such events through stronger oversight, improved traceability which benefits patients.

In consultations, consumer organisations and public authorities emphasised the value of higher safety standards and the transparency achieved under the new system. Patient organisations also supported robust rules as essential for safety and trust, while calling for proportionate approaches that minimise disruptions to care. In summary, **patients benefit from a stronger, more transparent, and more predictable safety system**, which over time is expected to improve trust in medical devices and prevent serious incidents. These benefits have not yet fully materialised but represent the long-term public health value of the Regulations as the implementation continues and reaches its full potential.

4.1.2.7. EU-level Governance: Costs & Benefits

Costs: For the Commission and EU-level governance structures, the Regulations entailed **substantial IT development and maintenance costs** for EUDAMED, alongside significant staff resources for managing MDCG coordination and regulatory/policy guidance development. For example, EUR 6 000 000 and 4 700 000 was allocated to EUDAMED development under the EU4Halth Work Programmes in 2023 and 2024

[218] Call for Evidence.

respectively.[219] The Commission also incurred costs for running joint assessments of notified bodies, facilitating harmonised implementation, and supporting expert panels which are run by the EMA. However, consultations handled by EMA under the Regulations have faced procedural inefficiencies, including unclear criteria for initiating consultations for certain device categories, variable quality of documentation submitted, and challenges in managing timelines and follow-ups.[220] These activities required sustained budgetary allocations and specialist staffing.

Benefits: At EU level, the reinforced governance system is enhancing harmonisation of how medical devices are regulated in the EU. The EU has maintained its global position in the MedTech sector and with stricter standards set, still influences international markets with continued reliance on the CE mark (see *section 4.1.1.3*). The increasing harmonisation of market surveillance, vigilance, and scientific support by the expert panels, as well as EUDAMED's potential once mandatory, contributes to improved oversight of device safety at EU level, which was previously fragmented or duplicated across national frameworks.

4.1.3. Coherence

The coherence of the Regulations was assessed by determining the complementarities or overlaps of provisions within and between the two Regulations (internal coherence) as well as their alignment to other EU legislation, policies and priorities, and international initiatives (external coherence).

*To what extent are the various elements of the MDR and IVDR coherent with one another (**internal coherence**)?*

The evaluation of the internal coherence between various elements of the Regulations identified some specific issues and revealed mixed perceptions from stakeholder groups. There was low agreement, ranging from 35% to 44%, regarding the internal coherence within each Regulation and their coherence with one another[221]. Whilst there is little evidence from other consultation activities[222] on major issues or specific examples of incoherent provisions, common recurring inconsistencies mentioned were regarding the use of terminology and contradictory requirements[223].

On **coherence between the Regulations**, **approximately 80-85% of provisions are the same or similar**[224]. Whilst this may suggest a high level of consistency, **inconsistencies remain**. This is especially where IVDR provisions are too extensively modelled on MDR

[219] European Commission website, *EU4Health annual work programmes 2023 and 2024*.
[220] 'EMA targeted survey', conducted in the context of the Targeted Evaluation of the MDR/IVDR.
[221] Public consultation.
[222] e.g. in the Call for Evidence and position papers.
[223] Call for Evidence – 87 out of 105 responses: 30 from Company/Business, 15 from Business Associations, 14 from Health Providers, 10 from EU Citizens, 8 from Other, 6 from Academic/Research Institutions, 2 from NGOs, 2 from Public Authorities.
[224] Input by external expert, see *Annex I*.

provisions, meaning IVDs and medical devices with a different nature or risks, are treated similarly. This is seen with the four-tier risk classification in both Regulations (see also *Annex VII, Figures 7* and *8*), as well as the respective conformity assessment procedures and level of notified body oversight. For example, a sterile class I medical device which may pose an infection risk due to direct patient contact, is treated in the same way as a sterile class A IVD, where the sterility ensures reagent stability and assay function and there is no patient contact. Additional examples of inconsistencies include[225]:

- The provision of **electronic instructions for use (eIFU**) by manufacturers to professional users is permitted for all devices for professional use under the MDR, whilst the IVDR excludes devices for near-patient testing from this possibility.
- Despite similar 'medium' risk levels, **Class IIa medical devices** can follow a simpler EU quality assurance certification, whilst this option is not available to **Class B IVDs** facing stricter certification requirements (under Annex IX IVDR)**.** This discrepancy creates challenges, especially for SMEs.
- The MDR recognizes the concept of **'well-established technologies'** and applies lighter requirements to them, but the IVDR lacks this concept, even though under the IVDR there are also many legacy products with a proven history of safe use.
- The cross-application of the **'surgically invasive'** concept from the MDR to the IVDR doesn't adequately account for the specific nature of IVDs, leading to excessive scrutiny for low-risk IVD performance studies, like routine blood draws. Consequently, these studies face stringent requirements akin to high-risk medical device procedures, creating unnecessary burdens without added value for patients.

As for **coherence within the Regulations,** the use of terms and definitions also show inconsistencies. Whilst some terms are defined, both Regulations also rely on key concepts which appear, but are not defined in the text, creating uncertainty for stakeholders. "**Intended purpose**" is defined in Article 2(12) (a key term for manufacturers when qualifying their product as a medical device) but is not distinguished from the related but undefined term "**intended use**". In addition, the terms "**significant change**" and "**substantial change**" in the Regulations are undefined and often confounded[226]. Though similar, they serve distinct functions under the MDR and are not interchangeable.

In addition, implementation experience has shown **inconsistencies between the MDR/IVDR requirements and their accompanying Annexes.** For example, the MDR **clinical evaluation** (Article 61(1)) suggests that confirmation of conformity with all relevant general safety and performance requirements (GSPRs) would need to be based on clinical data, whilst the corresponding Annex (Annex XIV) specifies that manufacturers need to identify the GSPRs that actually require support from clinical data in their clinical evaluation plan. Moreover, the MDR seems to mandate manufacturers to conduct clinical

[225] Input by external expert, see *Annex I.*

[226] "Significant change" affects a legacy device's market status under the transitional regime, while "substantial change" generally requires notified body review of a device or manufacturer's QMS before implementation.

evaluations, including a Post-Market Clinical Follow-up (PMCF) in all cases in Articles 10(3) and 61(11) and Annex XIV, Part B, whilst the Annexes II and II on post-market surveillance technical documentation allow manufacturers to justify why PMCF is not applicable. Finally, various manufacturer obligations are outlined in Article 10 of the Regulations by cross-referencing more detailed provisions. Aside from duplicating information, not all manufacturer's obligations are comprehensively listed.

*To what extent are the MDR and IVDR coherent with other EU (and, if applicable, national) interventions that have similar objectives (**external coherence**)?*

Consulted stakeholders showed a low level of agreement ranging from 4% to 34% on the alignment of the Regulations with other EU legislation, depending on the initiatives being compared[227] (see detailed views in *Annex V, section 3.5*). However, it's important to also consider some frameworks consulted on were adopted after the Regulations, and this along with other external factors can impact coherence levels.

This perceived low alignment also relates to the complexity between MDR/IVDR and other EU Regulations, and the need to avoid contradictory requirements or overlaps with horizontal frameworks[228] (see *Annex V*). Various EU regulations may apply to the market placement of medical devices or IVDs, affecting coherence. Whilst the MDR/IVDR in Article 1 establishes a hierarchy for some overlapping requirements (e.g. Medicinal Products Directive[229]) or applicability of complimentary regulations (e.g. the Machinery Regulation[230]), this is not true in all cases. Examples for improved alignment commonly called for across stakeholder groups were to the Artificial Intelligence Act[231] (AI Act), the Clinical Trials Regulation[232] (CTR) and environmental legislation, to reduce inefficiencies, administrative burdens and improve regulatory certainty. Reflections of MDR/IVDR coherence to a number of other EU frameworks are detailed below[233]:

- The **CTR** has coordinated processes, however no EU procedure for combined studies (involving both medical devices or IVDs and medicines) exists, requiring sponsors to submit separate applications under multiple frameworks. Greater alignment is needed to ensure innovative therapies can be developed safely and efficiently.
- Under the **AI Act,** medical devices can be classified as high-risk AI systems (Article 6(1) AI Act) leading to closer interactions with the MDR/IVDR. There is lack of clarity for manufacturers regarding conformity assessment and certificate timelines due to challenges related notified body designation for the purpose of single conformity assessment of MDAI (medical device with artificial intelligence).

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[227] Public Consultation.
[228] Call for Evidence, Position Papers.
[229] Regulation (EU) 2017/745, OJ L 117, 5.5.2017, pp. 1–175, ELI: http://data.europa.eu/eli/reg/2017/745/oj.
[230] Regulation (EU) 2023/1230, OJ L 165, 29.6.2023, pp. 1–102, ELI: http://data.europa.eu/eli/reg/2023/1230/oj.
[231] Regulation (EU) 2024/1689, OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj.
[232] Regulation (EU) No 536/2014, OJ L 158, 27.5.2014, pp. 1–76, ELI: http://data.europa.eu/eli/reg/2014/536/oj.
[233] Analysis supported by input from external expert see *Annex I*.

- The **Network and Information Systems II Directive**[234] **(NIS2)** establishes a cybersecurity framework for critical sectors in the EU. Some medical devices or IVDs will fall in scope if deemed 'critical during public health emergencies'[235], which may lead to dual reporting for certain manufacturers due to differing focuses of MDR/IVDR on device safety and NIS II on cybersecurity.
- The **European Health Data Space (EHDS) Regulation**[236] creates requirements for the interoperability of electronic health records systems that also medical devices which claim interoperability with such systems need to comply with. These requirements affect also manufacturers of such devices.
- The **Health Technology Assessment Regulation (HTAR)**[237] establishes a legal framework for the joint clinical assessment (JCA) and joint scientific consultations (JSC) of health technologies, including select medical devices and IVDs[238]. JCA reports analyse the relative effectiveness and safety of a health technology compared to existing ones and JCA procedural rules govern interactions with developers and notified bodies. Further alignment may be needed to simplify procedures and reduce duplications related to document submissions, in particular, via the use of EUDAMED.
- The **Batteries Regulation**[239] applies to medical devices and IVDs, requiring compliance with both frameworks. It mandates sustainability, battery-specific design, and environmental measures, while the MDR/IVDR focuses device-specific safety and performance requirements. Overlapping obligations can arise, such as the Batteries Regulation's requirement for user-removable and replaceable batteries versus the MDR/IVDR's need for sealed compartments in devices for safety, sterility, and performance. Whilst partial exemptions exist for certain devices, other manufacturers have to balance arguably contradictory requirements.
- The **Packing & Waste Regulation (PWR)**[240] and the MDR/IVDR have differing objectives creating challenges for the implementation of certain environmental requirements of the PWR. While MDR/IVDR focus on risk/benefit assessment, performance and safety, the PWR focuses on packaging recycling and minimisation. Exemptions exist for contact-sensitive packaging, but manufacturers may still face challenges in finding suitable non-recycled materials and suitable packaging design to ensure sterility is maintained

[234] Directive (EU) 2022/2555, OJ L 333, 27.12.2022, ELI: http://data.europa.eu/eli/dir/2022/2555/oj.
[235] Regulation (EU) 2022/123, OJ L 20, 31.1.2022, pp. 1–37, ELI: http://data.europa.eu/eli/reg/2022/123/oj.
[236] Regulation (EU) 2025/327, OJ L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj.
[237] Regulation (EU) 2021/2282, OJ L 458, 22.12.2021, pp. 1–32, ELI: http://data.europa.eu/eli/reg/2021/2282/oj.
[238] See Article 7 (1) point (c) of Regulation (EU) 2021/2282, OJ L 458, 22.12.2021, pp. 1–3, ELI: http://data.europa.eu/eli/reg/2021/2282/oj.
[239] Regulation (EU) 2023/1542, OJ L 191, 28.7.2023, pp. 1–117, ELI: http://data.europa.eu/eli/reg/2023/1542/oj.
[240] Regulation (EU) 2025/40, OJ L, 2025/40, 22.1.2025, ELI: http://data.europa.eu/eli/reg/2024/1781/oj.

To what extent are the MDR and IVDR coherent with (current) wider EU policies and priorities (external coherence)?

By supporting the safety and performance of medical technologies, the Regulations align to the **EU's wider health policy objectives** of strengthening health systems and improving citizens' well-being under the **One Health approach**[241]. In addition, the Regulations are included in and align with the **European Health Union Strategy**[242], which seeks to strengthen crisis preparedness, including via medical supplies availability. For example, the Regulations include emergency derogations for the availability of medical devices and IVDs based on patient or public health needs (Articles 59 MDR/54 IVDR) and provisions for non-emergency related reporting on supply interruptions and discontinuations (Article 10a MDR/IVDR, see also *section 4.1.1.3*). The latter is however not directly linked to management of public health crisis supplies by the EMA[243].

Based on the findings in *sections 4.1.1* (Effectiveness) and *4.1.2* (Efficiency), the Regulations do not seem to adequately align to the EU's current **competitiveness agenda**. To enhance competitiveness and sectoral resilience as outlined in the **EU Life Sciences Strategy**[244], the Commission announced in August 2025, a **simplification revision of the MDR and IVDR**[245]. This should improve the coherence of the Regulations to wider policy priorities of the Draghi report on EU competitiveness[246], the "Competitiveness Compass"[247] and the Simpler and faster EU communication Simplification and Implementation[248], which under the current framework is not being achieved. Finally, in terms of the EU's priority to close the innovation gap in its Competitiveness Compass and support SMEs (e.g. the EU start-up and scale-up strategy[249]) the current Regulations do not make special considerations for SMEs, who are mostly subject to the same rules and similar related costs/administrative burdens as large undertakings (see *section 4.1.2*).

To what extent are the MDR and IVDR coherent with international obligations and policies (external coherence)?

Whilst not holding obligations under international treaties in the medical devices field, the EU upholds its obligations under bilateral trade agreements and commitments to multilateral cooperation, notably in the IMDRF (see *section 4.1.1.3*). As an IMDRF Management Committee member, the EU actively participates in the development of globally harmonised principles and guidance and many IMDRF foundational concepts are

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[241] European Commission website, *One Health*.
[242] The European Health Union: Protecting our health together, COM/2024/206 final.
[243] Regulation (EU) 2022/123, OJ L 20, 31.1.2022, pp. 1–37, ELI: http://data.europa.eu/eli/reg/2022/123/oj.
[244] European Commission, *Commission launches new strategy to make Europe a global leader in life sciences by 2030*, Press release, 2 July 2025 https://ec.europa.eu/commission/presscorner/detail/en/ip_25_1686.
[245] European Commission Have Your Say webpage, *Medical devices and in vitro diagnostics – targeted revision of EU rule*: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14808-Targeted-revision-of-the-EU-rules-for-medical-devices-and-in-vitro-diagnostics-_en.
[246] Draghi, M., *The future of European competitiveness*, September 2024.
[247] A Competitiveness Compass for the EU, COM/2025/30 final.
[248] A simpler and faster Europe: Communication on implementation and simplification, COM/2025/47 final.
[249] The EU Startup and Scaleup Strategy Choose Europe to start and scale, COM/2025/270 final.

reflected in the Regulations. Although the Regulations align with IMDRF objectives, they lack direct links to IMDRF and other internationally recognised guidance documents. Whilst the Regulations embody the EU's commitment to international cooperation and regulatory convergence, further aligning EU regulatory implementation with IMDRF principles would strengthen global coherence and reduce unnecessary regulatory burden for innovators and manufacturers, while maintaining robust oversight and patient safety.

4.2. How did the EU intervention make a difference and to whom?

The Regulations have introduced a more robust legal framework for safety and clinical requirements for medical devices and IVDs, whilst establishing appropriate surveillance and vigilance mechanisms. Without reinforced EU intervention, diverging interpretation, transposition and enforcement of Directives and national laws would have persisted, hindering manufacturers' access to the EU single market and resulting in continued uneven health safety and protection levels for patients and users across the EU. The Regulations are in the process of positively impacting stakeholders, including industry and patients, who prefer **one EU regulation over** individual national legislations governing medical devices and IVDs[250]. Stakeholders also recognise the cost benefits in complying with one EU Regulation over different **rules at the national level**[251], however continued divergences in the interpretation and implementation of the Regulations mean the intended benefits are not yet realised.

While new requirements often come at increased cost, the Regulations offer strengthened requirements and, in some areas, greater predictability and legal certainty **for manufacturers** compared to the Directives, or to what could have been expected if Member Stated acted alone. A unified and strengthened framework, including centralised implementing tools (like the EUDAMED database) improves trust in the CE mark (both in Europe and globally) and credibility in the regulatory system, benefitting manufacturers selling CE marked devices and **patients**. Additionally, harmonised guidance and common EU procedures can improve consistency and level the playing field for manufacturers. As for competitiveness and innovation, a harmonised framework under the Regulations should have created a more even playing field internally (boosting competitiveness among EU players) and encouraged reliance from international partners (boosting global competitiveness of CE marked devices). Despite on-going EU activities to improve the situation (see *section 4.1.1.3)*, this potential is yet to be realised as the Regulations are still being implemented.

The Regulations also introduced infrastructure to increase the **harmonisation of notified body designation and oversight**. Whilst not proving fully effective (see s*ection 4.1.1.2*), including in terms of resources allocated at national and EU levels, this contributes to

[250] Public consultation, all stakeholder categories (except citizens) who strongly agree or agree: 93,3% (224/240) for MD – 64,6% (73/113) for IVD.

[251] Public consultation, stakeholder responses (except citizens): 49% or 117/240 and 50% or 119/240 respectively for the MDR; 58% or 65/113 and 56% or 63/113 respectively for the IVDR.

setting a more even playing field for both notified bodies and manufacturers. In addition, albeit operational uncertainty in their implementation is still lacking (see *section 4.1.1.1*), extensive Regulation requirements for notified body designation and conformity assessment activities have the benefit of setting common requirements across the EU, increasing trust and credibility in notified body issued certificates.

Significant EU added value comes from more centralised governance and **coordination mechanisms for Member States and the EU institutions,** under the Regulations. First, though not always seen as enhancing operational legal certainty (see *section 4.1.1.1*), MDCG discussions and guidance documents aid in implementing and enforcing the Regulations and tackling emerging challenges, such as on qualification and classification or new technologies. Second, strengthened provisions on market surveillance and reporting for national competent authorities, enhances information sharing among on devices and contributes to patient and user safety (see *section 4.1.1.4*). This coordination brings particular value when taking enforcement measures or related decisions against operators, which can be based on more comprehensive and less divergent information, thereby improving efficiency. By increasing vigilance and market surveillance collaboration and coordination, the Regulations ensure a more uniform approach to addressing patient and user safety risks across the EU, preventing divergence and inconsistent health protection levels among Member States (see *section 4.1.1.3*).

The Regulations have put in place a positive regulatory framework to ensure improved levels of **safety and performance of devices for patients and users**, regardless of the EU Member State in which they seek healthcare. Harmonised rules are recognised as improving patient safety[252] due to stricter requirements for clinical evidence (see *section 4.1.1.2*), reduced divergences in safety standards, improved coordination by competent authorities, and increased capacity for early risk detection. The Regulations are also increasing information on devices, via transparency and traceability mechanisms using EUDAMED, UDI and public reports, enabling patients and users across the EU to make more informed health decisions. However, the full potential for increased transparency, and therefore trust in the system remains unrealised due to delays in the necessary implementation tools (see s*ection 4.1.1.1*).

Finally, from an EU added value perspective, the proportionality of the Regulations lies in the fact that a single, harmonised EU framework can achieve a higher and more consistent level of safety and market oversight than fragmented national systems, even if this comes at (temporarily) high compliance costs. Around half of the stakeholders consulted believed that it was feasible to maintain adequately safe devices while reducing costs[253]. However, as shown in *section 4.1.2*, these costs are not always proportionate across actors, indicating that the efficiency of the EU-level intervention could be further optimised.

[252] Position papers.
[253] Public Consultation stakeholder responses (except citizens): 109/240 on the MDR; 48/113 on the IVDR.

4.3. Is the intervention still relevant?

The key objectives of the Regulations - to ensure high heath levels for patients and users, facilitate a smooth functioning internal market, support competitiveness and innovation, and achieving robust transparency for medical devices - remain important today.

Despite implementation challenges (see *section 4.1*), the Regulations are still relevant in ensuring that **users and patients benefit from safe and performant medical devices**. This is recognised by EU level healthcare and patient associations who state 'the objectives of the Regulations remain valid and that any new measures must be guided by the interests of patients and the public health'[254]. Stakeholders also suggest that the Regulations' stringent requirements, especially regarding clinical evidence, reporting and coordination of serious incidents, and the involvement of external expertise, have improved the regulatory framework[255]. Some stakeholders however question the Regulations' long-term efficacy in achieving safety objectives. Less than half of respondent to the study on governance believed the Regulations will ensure safe and performant devices in the next 5-10 years[256]. However, this could also be linked to effectiveness and efficiency in the implementation of the Regulations.

The Regulations seek to ensure that **patients, users, and all key players have access to transparent information on the devices**, such as on their intended purpose, how to use them and the associated risks. A majority of consulted citizens agreed they have access to information on the device's use and associated risks.[257] Nevertheless, representatives of healthcare professionals noted that whilst EUDAMED will provide more information on devices, it will still not contain data needed to make informed clinical decisions (e.g. clinical evidence on high-risk devices, safety reporting outcomes)[258] – a perspective echoed in the Call for Evidence feedback[259]. Stakeholders overall supported greater transparency through EUDAMED, UDI, and public access to clinical data[260]. This shows that the objective of transparency of the Regulations remains a priority across stakeholder groups.

The objectives of the Regulations related to the **smooth functioning of the internal market and the support to competitiveness and innovation** in the sector remain relevant. As the second largest market globally, the European medical technology sector plays a key role in strengthening the EU's strategic autonomy and global positioning.

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[254] Biomedical Alliance in Europe (BioMed Alliance), European Patients Forum (EPF), European Association of Hospital Pharmacists (EAHP), European Hospital and Healthcare Federation (HOPE), *Open letter: Meeting the needs of patients, healthcare practitioners and hospitals in the targeted revision of the Medical Devices Regulation*, 11 September 2025.

[255] Reality check workshop with healthcare professionals, users and patients.

[256] Study on governance.

[257] Citizens responses to the PC: varying by device group, 66,67% -75% largely agreed/agreed there was access to information on devices and device usage; 40% - 62,5% largely agreed/agreed that device risk information was sufficient.

[258] Reality check workshop with healthcare professionals, users and patients.

[259] Call for evidence – 34 out of 121 respondents: 10 Business, 8 Health Providers, 6 Business Associations, 4 EU Citizens, 3 NGOs, 2 Academics, 1 Public Authority.

[260] Position paper.

However, stakeholders do not consider the Regulations effective in stimulating innovation, viewing the current framework as disproportionate in some areas, particularly disadvantaging SMEs and start-ups,[261] and lacking centralised, harmonised regulatory and scientific early guidance to manufacturers[262].

In terms of meeting the **evolving needs of patients in the EU,** the Regulations are not seen as meeting their full potential**.** In particular, for **niche and orphan devices** for small populations with low-demand, stakeholders question whether the regulatory framework sufficiently supports current needs and technological developments. Applying the same regulatory requirements as for other devices (with higher demand) is seen as disproportionate and misaligned with the policy of ensuring access to critical devices. Stakeholders therefore advocate for dedicated regulatory pathways to better align with the evolving patient needs in the EU.[263] In terms of addressing patient needs with **emerging health challenges**, stakeholders indicate limited relevance of the Regulations. Nearly 56% of public consultation respondents for medical devices and 60% for IVDs believe the current framework falls short,[264] echoed also in the Call for Evidence[265].

Considerable **scientific and technological developments** (e.g. digitalisation, artificial intelligence, medical device software, wearables and robotic surgery) are transforming the medical devices sector. Since the adoption of the Regulations, many of these advancements have progressed, yet the Regulations are not perceived as sufficiently supporting **innovation**[266], which may hamper innovative devices reaching the EU market[267,268]. Overall, stakeholders agree that the complexity of the Regulations hinders innovation, making the EU less attractive for clinical research and product launches, and therefore lack relevance to today's needs. They call for a more balanced and harmonised approach, with regulatory simplifications to foster innovation and ensure timely access to new technologies[269].

To what extent are the processes and mechanisms of the MDR and IVDR still relevant in view of the objectives?

The Regulations formalised and expanded several processes and mechanisms from the Directives and introduced new ones, including a stricter joint assessment process for

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[261] Call for evidence – 65 out of 330 respondents: 30 from Company/Business, 15 from Health Providers, 10 from Business Associations, 5 from EU Citizens, 3 from Academic/Research Institutions, 2 from Other.
[262] See note 111, page 21.
[263] Position paper, Call for Evidence.
[264] Public consultation.
[265] Call for evidence – 48 out of 330 respondents: 48 feedback to the Call for Evidence discussed misalignment of the Regulations with emerging technologies and needs: 25 from Company/Business, 10 from Health Providers, 5 from Academic/Research Institutions, 4 from NGOs, 3 from Other, 1 from EU Citizens.
[266] See note 265, pg 49.
[267] 60% of stakeholders in a study's survey disagreed that the regulatory framework fosters innovation (Diana Vertelkiene, Yves Verboven, Liz Rezaglia, Ana Duc, *MILESTONE MS16- Second Annual MD/IVD Industry pulse report*, Project: 101101269 – NoBoCap - EU4H-2022-P), 2025.
[268] See note 111, page 21.
[269] Call for evidence – 47 out of 253 respondents: 20 from Company/Business, 10 from Health Providers, 7 from Business Associations, 5 from Academic/Research Institutions, 3 from NGOs, 2 from EU Citizens.

notified body designation, robust post-market oversight mechanisms (e.g. coordinated safety assessments) and pre-market review mechanisms (e.g. coordinated assessments of clinical investigations). Whilst not always fully effective or efficient, *(*see *sections 4.1.1.2, 4.1.1.4 and 4.1.2*), these processes remain relevant to achieve the Regulation's patient safety and health protection objectives. The Regulation's transparency and traceability tools, such as UDI and EUDAMED, further support informed healthcare decisions, for users and patients, remaining essential to achieve the Regulation's transparency objectives. However, certain processes and mechanisms have resulted in unintended consequences that hamper the goals of a smooth functioning internal market, supporting competitiveness and innovation and reducing efficiencies whilst enduring device availability (see *section 4.1.1.5).*

5. WHAT ARE THE CONCLUSIONS AND LESSONS LEARNED?

5.1. Conclusions

The performance of the Regulations to date must be viewed in the wider context of its on-going implementation and the extended transitional periods. The evaluation builds on a range of evidence sources. Limitations, including on data availability and cost quantification, are identified in the methodology. In this context, the evaluation draws conclusions regarding the Regulation's effectiveness, efficiency, coherence, relevance and added value which offer lessons for future improvements. Overall, the benefits of the Regulations for patients and healthcare systems are materialising by strengthening device safety and performance and increasing transparency. However, this comes at a high and often disproportionate cost vis-à-vis compliance requirements, with administrative complexity and uneven progress across objectives and actors.

Effectiveness

The Regulations have introduced stricter requirements for the designation and oversight of notified bodies, the conduct of conformity assessment activities, the generation of clinical evidence supporting the safety and performance of devices, the post-market oversight of devices, and increased transparency requirements. They have also strengthened harmonisation and coordination mechanisms across all governance levels. As a result, whilst **not always effective** in achieving its objectives to date, the EU regulatory framework for medical devices **benefits from a more robust infrastructure for safe and performant medical devices**, with enhanced safeguards to respond more effectively to potential safety risks and increased access to information. Several **unintended consequences** have also been identified, namely; implementation delays, an increased administrative burden, longer timelines and increased costs to achieve market access, inconsistent application of regulatory requirements, and a complex regulatory governance structure. These are partially due to external factors, such as the COVID-19 pandemic, but also to due structural drivers, such as overlapping requirements, slow guidance development and limited notified body capacity. Together, these contribute to a **perceived unpredictability and disproportionality** of the system, undermining trust, including of

healthcare professionals, patients and users. Ultimately, this results in a **decrease in the availability of certain devices**, particularly innovative and niche devices, thus having a negative impact on both competitiveness – including at global level - and the protection of health for patients.

Progress towards the objectives of the Regulations remains uneven across key areas. **Legal certainty, transparency for all actors and citizens, and trust** are advancing to different levels, but remain unfulfilled. The complexity of the frameworks and the need for further clarification of legal provisions continue to create operational uncertainty among stakeholders. Transparency and trust in the regulatory system are not yet achieved but are expected to improve once remaining infrastructure and tools are fully functional, with a positive perspective to reach the objectives by the end of the transition period. Objectives related **high health protection** via **post-market surveillance, vigilance, and market surveillance** show better progress. Evidence shows improved traceability, oversight, and patient safety, and these objectives are expected to be largely achieved by the end of the transition periods. Concerning **notified bodies, conformity assessment, and clinical evidence**, notified body capacity under the MDR has largely stabilised, but remains to be determined under the IVDR. Harmonisation of conformity assessment practices across notified bodies and Member States is still limited, thus making it uncertain whether full alignment can be achieved by the end of the transition periods. Clinical evidence is increasing however, the intended robustness and availability of clinical evidence and data under the Regulations is not yet achieved.

The objectives of ensuring a **smooth market functioning and level playing field and supporting competitiveness and innovation** (taking into account the specificities of SMEs), have not yet been met. Regulatory complexity and uneven application across Member States have constrained the ability of manufacturers – particularly SMEs – to innovate and compete on equal terms. This has also impacted device availability, and the ability to cater for specific patient needs. Although the EU market remains the second largest globally and a leading originator of patents, the pace of innovation appears slower than in more agile markets, such as the US, suggesting a gradual loss of competitiveness. While the framework has the potential to enhance the EU's competitiveness on the global stage, this will require greater predictability, international alignment, and support for smaller actors to sustain **innovation** and market participation. Regarding **simplification and streamlined procedures**, the existing structure of governance have facilitated collaboration, but remain resource-intensive and slow to deliver outputs. Without further structural adjustments, this is unlikely to improve.

Finally, the **extensions of the transition periods** alleviated the immediate risks of device shortages and capacity pressures on notified bodies, particularly under the MDR, though projecting the longer-term effects remains difficult. They also provided manufacturers additional time to adapt and ensure continued availability of critical devices. However, while the extensions offered the necessary temporary relief, they have had limited effects on resolving the underlying hurdles presented by the Regulations and device availability

issues remain. If left unresolved, this could have more serious consequences for patient care and particularly for vulnerable patient groups.

Efficiency

The Regulations have brought **benefits for patients** when it comes to introducing **stronger safety requirements, better evidence standards and transparency**, with potential to increase system trust overtime. Nevertheless, when analysing whether **compliance costs** increased compared to the Directives – which was an expected outcome taking into account the higher ambition of the new framework – evidence shows that the **gains are uneven**, especially for manufacturers. The **distribution of costs is uneven**, with SMEs and manufacturers of niche devices bearing a disproportionate share, while larger operators are better able to absorb the compliance effort. This has contributed to a reduced availability of devices, particularly for rare diseases and niche products, with some manufacturers withdrawing from the market due to high compliance costs and limited notified body capacity. These effects risk offsetting some of the intended benefits such as a high level of patient protection. While the Regulations are expected to deliver benefits that ultimately outweigh their costs, **the balance between regulatory burden and public health gains could be further improved**. Streamlining procedures, enhancing coordination, and reducing unnecessary administrative complexity would help ensure that efficiency gains accompany the strengthened safety achieved under the new framework.

Coherence

Overall, **provisions between the Regulations** (MDR and IVDR) and within the Regulations **are coherent** (internal coherence), **however inconsistencies remain** in terminology and requirements. Between the Regulations, a large majority of provisions are similar; however, discrepancies exist, especially where requirements or concepts are cross-applied from the MDR to the IVDR (despite differing product risks and nature), or allowances are made in the MDR (for electronic IFUs or ‘well-established technologies’) but not in the IVDR, creating implementation challenges. Additionally, within the Regulations, undefined terms and inconsistencies between the Regulations' requirements and Annexes further complicate implementation. In terms of **external coherence, while no major incoherences were identified** between the Regulations and other EU frameworks, stakeholder **perception of alignment was low**, and highlighted the need to avoid contradictory requirements or overlaps especially with digital, environmental and other health legislations. While the Regulations align with EU’s health policy objectives by supporting medical technology safety and performance, they fall short on the EU's competitiveness agenda. Finally, the Regulations reflect the EU’s commitment to internation cooperation, especially through participation in the IMDRF, yet strengthening alignment with international principles could reduce regulatory burdens and enhance global coherence.

EU Added value

Stakeholders prefer a unified EU Regulation over individual national laws for improved consistency and potential for cost efficiency. While the Regulations have streamlined requirements, national implementation practices still vary. Despite increased costs for manufacturers, the Regulations provide the infrastructure and potential for greater predictability, legal certainty, and enhanced patient safety through detailed safety requirements and harmonised procedures. Strengthened safety requirements and transparency tools, including UDI and the EUDAMED database contribute to enhancing credibility, trust, and international competitiveness of CE-marked devices. Although not fully achieved, harmonisation of notified body designation and oversight improves consistency in applying requirements, strengthening certificate credibility and showing EU added value of the Regulations. Finally, enhanced coordination among national authorities boosts device safety monitoring, ensuring uniform patient protection across Europe.

Relevance

The Regulations remain relevant to their core objectives of ensuring patient safety, public health protection, transparency, and the smooth functioning of the internal market. These goals continue to address fundamental societal needs, particularly through strengthened evidence requirements, oversight mechanisms, and traceability measures. However, the evaluation shows that objectives linked to innovation, technological development, and competitiveness – especially for SMEs – face increasing challenges, as certain regulatory requirements are not yet fully adapted to the evolving technological and market realities. Stakeholders widely agree that while the main objectives remain valid, implementation can limit innovation, development of niche devices, and the uptake of emerging technologies. Uneven impacts across economic operators also point to the need for greater proportionality and flexibility. Overall, the Regulations provide a relevant framework for ensuring the safety and performance of medical devices, but targeted adjustments are needed to ensure that they remain fit for purpose in a rapidly changing technological and healthcare environment. Finally, while the Regulations' processes and mechanisms remain relevant in view of the objectives, certain provisions have led to unintended consequences that limit their full potential.

5.2. Lessons learned

Stakeholders have consistently emphasised the need to **streamline and simplify the regulatory governance framework** for medical devices and IVDs. Harmonised notified body designation and oversight, centralisation and strengthening of regulatory governance structures, and improved coordination amongst authorities and notified bodies are seen as key to reduce fragmentation and ensure a more cohesive regulatory framework. In addition, streamlining the work of the MDCG and its technical sub-groups, and moving from consensus to more effective decision-making mechanisms would result in a more efficient and responsive system, capable of delivering outcomes in a timely manner.

Moreover, the **increased administrative burden** resulting from the Regulations could be addressed by **streamlining reporting obligations** as well as avoiding duplication and overlapping of reports and their assessment. The predictability of the system could be enhanced by allowing early dialogue with notified bodies, ensuring clear certification timelines, and addressing resource-intensive and lengthy consultation procedures. In addition, addressing the perceived disproportionality in the system, particularly with low and medium risk devices, and developing **flexible regulatory pathways for innovative and niche devices**, could improve the competitiveness of the Union market, while ensuring the continued availability of devices for diverse patient populations and emerging healthcare needs. Finally, by further **advancing digitalisation initiatives**, such as electronic instructions for use (e-IFUs), electronic labelling, and the development of electronic submission systems, the regulatory framework could become more accessible, efficient, and aligned to evolving sectoral needs.

Overall, lessons learned from the evaluation will provide context to the Commission's on-going simplification of the Regulations, planned for adoption in December 2025, which aims to enhance competitiveness of the sector, and support innovation whilst making safety requirements more cost-efficient, predictable and proportionate.

ANNEX I: PROCEDURAL INFORMATION

Lead DG

The European Commission's Directorate-General (DG) for Health and Food Safety is the lead DG for this targeted evaluation (PLAN/2024/451). The targeted evaluation was included in the Commission Work Programme 2025 (COM (2025) 45 final).

Derogations and justification

No derogation was requested.

Organisation and timing

Work on the targeted evaluation started in 2024. The Call for Evidence document and the Public Consultation were open for contributions from 12 December 2024 to 21 March 2025.

An interservice coordination group (ISCG) involved representatives from DG BUDG, DG COMP, DG CNECT, DG ENER, DG ENV, DG GROW, DG HERA, DG RTD, DG SANTE, DG SG, DG TRADE, SJ (Legal Service) and the JRC, and held 8 meetings between July 2024 and November 2025. The ISCG contributed to the targeted evaluation by ensuring its scope is comprehensive and its approach sound and robust.

Consultation of the Regulatory Scrutiny Board

The targeted evaluation was not selected for scrutiny by the Regulatory Scrutiny Board.

Evidence, sources and use of expertise

Members of the Medical Device Coordination Group (MDCG) were regularly consulted on the targeted evaluation. The Commission informed the members of the planning of the targeted evaluation in its May 2024 MDCG meeting. The targeted evaluation has been discussed in every MDCG meeting since then (6 MDCG meetings), with a dedicated workshop during the meeting of the MDCG in February 2025.

In addition to the contributions to the **Call for Evidence and the Public Consultation**, the Commission organised targeted consultation activities informing the targeted evaluation. These include a series of **targeted surveys** tailored to specific stakeholder groups (Economic Operators, Notified Bodies and National Competent Authorities, EMA), **two reality checks workshops** (one workshop with manufacturers, one workshop with healthcare professionals, patients and users) as well as the organisation and participation to events/conferences, such as the information session on the evaluation for regulators from non-EU countries. The targeted evaluation was also based on the analysis of **position papers and written submissions** from stakeholders as well as **desk research and documentary analysis**, drawing on official reports, MDCG guidance and previous evaluations. For more details, see *Annex V – Synopsis Report*.

Furthermore, the Commission launched external studies and benefited from insights from external experts:

- One study (Ernst and Young, *Study on Regulatory Governance and Innovation in the field of Medical Devices - Final report*, Publications Office of the European Union, 2025, DOI:10.2875/8995410) analysed the **regulatory governance and innovation in the field of medical devices**. Several consultation activities took place in the context of this study, including one **workshop dedicated to SMEs**.
- Another **study** (Technopolis, *Study supporting the targeted evaluation of the MDR and IVDR - Final report*, December 2025, under preparation) analysed some of the **evidence collected** in the context of the **consultation activities** and performed case studies.
- One external expert supported the evaluation by providing **overall methodological support**.
- Another external expert provided **input to an analysis of the coherence** of the Regulations.

Each source contributed distinct strengths: targeted surveys yielded structured numerical data; open consultations captured perceptual and contextual insights; and desk research provided factual and institutional background.

All methodological details on the preparation, sampling and data processing of these sources are presented in ***Annex V (Methodological section of the Stakeholder Consultation)***, in line with *Tool #54* of the Better Regulation Toolbox ("Analysing data and informing policymaking").

ANNEX II. METHODOLOGY AND ANALYTICAL MODELS USED

1. Introduction

This methodological annex provides a transparent and detailed description of how the targeted evaluation of the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR) was designed and conducted. It complements the analytical findings presented in the main Staff Working Document (SWD) or the 'Evaluation Report' and follows the methodological standards set out in the *Better Regulation Guidelines* and *Better Regulation Toolbox* (2023 edition).

The annex explains how evidence was structured and synthesised across the five evaluation criteria of effectiveness, efficiency, coherence, relevance, and EU added value. It describes how the analytical work was anchored in a formal evaluation matrix, how mixed sources of evidence were integrated through triangulation, and how the results were assessed using a transparent scoring system. It also sets out the limitations of the available data, the measures taken to mitigate these, and the approach used to manage uncertainty and ensure the robustness of results. It also explains the specific analytical framework used to assess efficiency and the relationship between costs and benefits, consistent with the Better Regulation Toolbox (Tools #57–#61).

The annex does **not** describe the data-collection process itself. Details on the preparation, dissemination and processing of the consultation activities - including the Call for Evidence, Public Consultation, and the targeted surveys are presented separately in ***Annex V (Methodological section of the Synopsis Report)***.

Overall, this annex demonstrates that the evaluation has been implemented in full coherence with the Commission's *Better Regulation* principles of transparency, proportionality, and evidence-based policymaking (Tool #4).

2. Evaluation design

2.1. Conceptual basis

In accordance with *Tool #45* ("What is an evaluation and when it is required") and *Tool #46* ("Designing the evaluation"), the analytical design follows a structured sequence linking the intervention logic, evaluation questions, judgement criteria and indicators.

The revised intervention logic for the MDR and IVDR provides the backbone for the evaluation. It maps how the Regulations' inputs (legislative provisions, governance structures and resources) are intended to produce outputs (reinforced certification procedures, clinical investigation/performance studies and post-market surveillance), leading to results (harmonised oversight, improved transparency, strengthened safety) and ultimately to long-term impacts (patient protection, public trust, competitiveness and innovation) (see *Figure 2* in the Evaluation Report).

From this logic, an evaluation matrix was developed in line with *Tool #46* and *Tool #47* ("Evaluation criteria and questions"). The matrix ensures that each of the five evaluation criteria is operationalised

through clear, non-overlapping questions and that each question is supported by explicit judgement criteria, measurable indicators and identified sources of evidence.

- **Judgement criteria** define the qualitative or quantitative standards against which progress is assessed.
- **Indicators** provide measurable signs of change or achievement, including both quantitative data (e.g. numbers of certificates, costs, disputes) and qualitative information (e.g. stakeholder perceptions, consistency of interpretation).
- **Data sources** identify the datasets and evidence streams used to answer each question.
- **Points of comparison** are references against which the answers to the evaluation questions are assessed.

The evaluation matrix was used as an organising tool throughout the evaluation process: it guided the structure of data collection, ensured full coverage of the intervention logic, and allowed for systematic comparison of evidence across themes and stakeholder groups. A full version of the matrix, including all evaluation questions and indicators, is provided in *Annex III*.

2.2. Grouping of effectiveness indicators

Effectiveness covers a wide spectrum of objectives from legal clarity and governance processes to safety outcomes and market functioning. To make this complex analysis comprehensible, evaluation questions were grouped into five thematic sections. The grouping reflects the internal structure of the regulatory framework and the logical sequence of actions and results. This approach is consistent with *Tool #47* on proportionality and coherence in evaluations, which recommends thematic grouping where multiple questions address interrelated mechanisms.

2.2.1. Legal certainty, transparency and trust

Motivation:
Transparency is a core element of both the MDR and IVDR's effectiveness. It underpins stakeholder trust, facilitates accountability, and supports informed decision-making by patients, professionals and industry. This section assesses to what extent the Regulations have increased openness, accessibility and reliability of information (e.g. through EUDAMED, SSCPs, UDI, and publication of expert opinions). In practice, transparency contributes indirectly to legal certainty (by clarifying regulatory expectations) and directly to trust (by allowing external verification).

Evaluation question covered:

- How successful have the MDR and IVDR been in contributing to its general objectives in terms of ensuring a high level of transparency on medical devices for all actors and citizens?

2.2.2. Notified Bodies, conformity assessments and clinical evidence

Motivation:
The protection of health is achieved primarily through the robustness of pre- and post-market

regulatory controls. This section focuses on the mechanisms that directly ensure safety and performance: the designation and oversight of notified bodies, the conduct and consistency of conformity assessments, and the generation of clinical and performance evidence. Strong and predictable conformity assessments, based on sound clinical data and evidence, are the cornerstone of achieving the general objective of high health protection. This section therefore captures how well the MDR/IVDR translate the legislative ambition for safety into operational reality.

Evaluation question covered:

- How successful have the MDR and IVDR been in contributing to its general objectives in terms of ensuring a high level of protection of health for patients and users?

2.2.3. Market functioning and level playing field

Motivation: This section examines whether the Regulations have achieved their internal market objectives by enabling uniform application across Member States and reducing fragmentation. It covers elements such as market access, innovation and competitiveness, international cooperation, the availability of devices and the Regulation's capacity to address specific needs of patients and users. The focus is on whether the Regulations have preserved the free movement of goods while maintaining safety standards—balancing regulatory control with efficiency and predictability.

Evaluation question covered:

- How successful have the MDR and IVDR been in contributing to its general objectives in terms of ensuring a smooth functioning of the internal market as regards medical devices?

2.2.4. Post-market surveillance, vigilance and market surveillance

Motivation: Post-market surveillance (PMS), vigilance and market surveillance are integral to maintaining health protection over the lifecycle of devices. This section addresses post-market controls and the *ongoing* capacity of the system to detect and manage risks once devices are in use. Together, the sections 'Notified Bodies, conformity assessments and clinical evidence' and 'Post-market surveillance, vigilance and market surveillance' jointly operationalise the "health protection" objective across the device lifecycle—prevention before market entry, and monitoring after placement on the market.

Evaluation question covered:

- How successful have the MDR and IVDR been in contributing to its general objectives in terms of ensuring a high level of protection of health for patients and users?

2.2.5. Simplification and streamlined procedures

Motivation: Simplification and governance determine the capacity of the system to deliver on its objectives efficiently. Simplification refers not only to reducing administrative complexity but also

to improving clarity of roles and procedures. Governance encompasses the functioning of coordination structures such as the Medical Device Coordination Group (MDCG) and the allocation of resources at EU level. Analysing these aspects together allows the evaluation to assess how institutional design influences effectiveness and whether the Regulations have promoted or hindered coherent implementation.

This section structure ensures thematic coherence and allows synthesis across questions with related causal pathways. It also provides a foundation for balanced aggregation of evidence in the overall scoring.

3. Analytical framework

3.1. Triangulation and mixed-methods approach

As no single source of evidence provides a complete picture, the evaluation applied a mixed-methods design combining quantitative and qualitative information, as recommended in *Tool #48* ("Conducting the evaluation"). In addition to the general analytical framework described above, the evaluation applied a specific approach to assess efficiency and the balance between costs and benefits, consistent with the Better Regulation Toolbox (Tools #57–#61).

Triangulation served to increase the validity of findings by cross-verifying results from multiple independent sources. It was applied along three complementary dimensions:

- **Horizontal triangulation:** comparison of different stakeholder groups' perspectives on the same issue - for example, contrasting manufacturer perceptions with those of notified bodies or national competent authorities (NCAs).
- **Vertical triangulation:** linking perceptions to empirical data, such as comparing survey opinions on costs with numerical data.
- **Temporal triangulation:** assessing consistency of evidence across time periods, particularly for indicators that span the transition from the previous Directives to the new Regulations.

In practice, triangulation meant that a finding was treated as robust only if it was supported by at least two distinct and independent sources. In some cases, this was not possible and in those cases the SWD outlines limitations or that the finding could not be robust. Divergences between sources were not averaged out but are clearly outlined in the text.

The mixed-methods approach also follows *Tool #57* ("Methods to assess costs and benefits"), which recommends combining quantitative and qualitative evidence when full quantification is not feasible. Quantitative data offered measurable evidence of trends (e.g. average notified bodies fees, survey percentages), while qualitative inputs provided explanation and nuance, helping to interpret why stakeholders experienced impacts differently.

3.2. Scoring system

To integrate heterogeneous evidence into a coherent assessment, the evaluation of the five criteria applied a **five-point ordinal scale**, as recommended in *Tool #47* ("Evaluation criteria and questions"). This system enables transparent synthesis while maintaining proportionality.

Score	Interpretation	Typical evidence pattern
++	Strong positive impact	Consistent quantitative improvement and strong qualitative consensus
+	Some positive impact	Majority of evidence positive, some reservations
0	Neutral or mixed	Evidence divided or inconclusive
-	Some negative impact	Majority of evidence negative, but not overwhelming
--	Strong negative impact	Convergent evidence of substantial adverse impact

Scoring was performed sequentially:

1. Evidence was reviewed per evaluation question using the matrix.
2. Judgement criteria were assessed individually.
3. A narrative synthesis combined quantitative and qualitative elements.
4. An overall score was assigned, supported by short justifications.

The scores are **interpretative**, not mechanical. Percentages or averages from surveys were not automatically converted into scores; rather, they were weighed alongside qualitative information and triangulated findings. This qualitative scoring ensures that conclusions remain proportional to the strength of the evidence and avoid over-precision where data are limited.

The use of a unified scoring scale across all sections facilitated comparison between different impact areas - such as efficiency versus effectiveness - and enabled synthesis into a global assessment per evaluation criterion.

3.3. Efficiency analysis and assessment of costs and benefits

In addition to the general analytical framework described above, the evaluation applied a dedicated approach to assess **efficiency** and the balance between **costs and benefits** of the MDR and IVDR. This approach follows the *Better Regulation Toolbox* guidance (Tools #57–#61) on analysing costs, benefits and proportionality in evaluations.

The efficiency assessment examines how the objectives of the Regulations relate to the resources required to achieve them. It does not focus solely on whether compliance costs have increased compared to the previous Directives — an outcome that was expected given the higher ambition of the new framework — but also on whether these costs appear proportionate to the benefits achieved in terms of patient safety, public-health protection, transparency and market functioning.

3.3.1. Methodological approach

The efficiency analysis combines quantitative and qualitative methods, in line with the principles of the *Better Regulation Guidelines*, which recommend considering both measurable and non-monetary dimensions of efficiency.

Evidence was drawn from the targeted surveys of economic operators, notified bodies and national competent authorities, and of the EMA, as well as from the Call for Evidence, Public Consultation, position papers and reality check workshops. This evidence base made it possible on some of the topics to triangulate stakeholder perspectives while recognising the heterogeneity of responses.

Three analytical distinctions guided the approach:

1. **Direct and indirect costs**
    - *Direct costs* are those explicitly incurred for compliance with regulatory obligations, including notified bodies fees for certification, preparation of technical documentation, clinical or performance evaluations, and establishment of post-market surveillance (PMS) systems.
    - *Indirect costs* are less directly measurable but equally relevant, such as delays in certification leading to postponed market entry, opportunity costs where resources are diverted from innovation to compliance activities, and broader market effects such as devices availabilities, i.e. portfolio reductions or product withdrawals.
2. **Monetary and non-monetary dimensions:** Quantitative evidence was used wherever robust data were available — for example, average certification costs/fees. Many aspects of efficiency, however, are qualitative in nature, including administrative complexity, procedural delays and predictability of implementation, and many burdens are reported as resource diversion, added complexity or workflow delays. Quantitative and qualitative evidence were therefore treated as complementary: quantitative data provide order-of-magnitude indications, while qualitative inputs help interpret context and drivers. Benefits such as trust and transparency are captured only qualitatively.
3. **Proportionality and distribution of impacts:** Efficiency also depends on how costs and benefits are distributed among actors. Evidence suggests that small and medium-sized enterprises (SMEs) bear proportionally higher compliance costs than larger firms and that IVDR requirements pose specific challenges for laboratories and health institutions (e.g. in house devices). These distributional aspects were incorporated into the qualitative synthesis and the proportionality judgement.
4. The analysis also recognises the importance of distinguishing between **transitional and structural** costs, since the MDR and IVDR are not yet fully implemented but most stakeholders expect elevated costs to remain.

3.3.2. Typology of costs and benefits considered

The evaluation distinguishes several categories of costs and benefits, aligned with the intervention logic and evaluation matrix:

- **Compliance costs for manufacturers and economic operators**: including technical documentation, clinical and performance evaluations, notified bodies certification and maintenance fees, and PMS/vigilance activities.
- **Compliance costs for healthcare providers (e.g. health institutions and laboratories)**: particularly documentation and validation requirements for in-house devices.
- **Compliance costs for notified bodies, national competent authorities and EU structures**: including notified bodies designation and oversight, staffing for national competent authorities, and EU-level, including IT and coordination costs (e.g. EUDAMED, MDCG).
- **Indirect costs**: market-level effects such as certification delays, opportunity costs of compliance, and consequences for device availability.
- **Benefits**: improved safety (health) and quality of devices, stronger transparency and traceability, more harmonised oversight across Member States, and increased trust in CE marking.

This typology structures the analysis and allows for a balanced comparison of costs and benefits across stakeholder groups.

3.3.3. Evidence base

Quantitative evidence on direct compliance costs was obtained primarily from the notified bodies and economic operators surveys. These provided indicative cost ranges and averages per certificate type, company size and where available, per device risk class.

Qualitative evidence was drawn from the consultation activities (Call for Evidence, Public Consultation, and position papers), which highlighted perceived cost drivers, administrative burdens and expected benefits such as enhanced safety and transparency.

The analysis relied on triangulation between these sources rather than direct aggregation. Quantitative estimates were treated as illustrative indicators, while qualitative information was used to interpret patterns and distributional effects.

3.3.4. Interpretation and proportionality

Given the incomplete data coverage and ongoing implementation of the Regulations, the efficiency analysis does not attempt to calculate a quantified cost–benefit ratio. Instead, it assesses whether the available evidence indicates proportionate relationships between resource inputs and achieved or expected outcomes.

Certain benefits - for example, improved safety, transparency and trust - are expected to materialise progressively over time. Conversely, several cost impacts, particularly for SMEs and niche

manufacturers, are already visible. The evaluation therefore interprets efficiency results with caution and in a proportional manner, recognising that the overall balance between costs and benefits may evolve as implementation matures and as data become more comprehensive.

3.3.5 Limitations

The main limitations affecting the efficiency analysis are consistent with those of the broader evidence base:

- Limited comparability of cost data across actors and device types;
- Absence of a quantitative baseline under the previous Directives;
- Uneven representativeness of survey samples; and
- Ongoing implementation of MDR/IVDR provisions, which means that some costs are transitional, and some benefits have yet to materialise.

To mitigate these limitations, the evaluation relied on triangulation of evidence, basic plausibility checks of quantitative results and cautious, proportional interpretation of incomplete information. These steps helped maintain the credibility and balance of the efficiency assessment despite inherent data gaps

4. Limitations and mitigating measures

Recognising and managing limitations is essential for methodological transparency (see *Tool #65*, "Uncertainty and sensitivity analysis"). The main constraints affecting this evaluation were as follows:

1. **Representativeness of open consultations:** Participation in the public consultation and Call for Evidence was voluntary and self-selected. Results therefore represent stakeholder perceptions rather than statistically representative opinions. Their role in the analysis is to contextualise, not to quantify, broader stakeholder sentiment.
2. **Heterogeneity and coverage of targeted surveys:** The targeted surveys reached a high share of notified bodies and a broad sample of national competent authorities and economic operators, but coverage across device categories and Member States was uneven. Aggregated averages were therefore interpreted cautiously, and sensitivity checks were applied to control for outliers.
3. **Absence of comprehensive baseline data:** Systematic pre-2017 data on costs, benefits and administrative burdens are lacking, making precise before/after comparisons not possible. The evaluation instead used qualitative benchmarks drawn from previous studies and stakeholder recollections.
4. **Attribution complexity:** Developments in the medical device sector reflect a combination of regulatory, economic and external factors (e.g. COVID-19, also affecting supply-chain pressures). The evaluation therefore assesses the *consistency* of observed trends with the Regulations' intervention logic rather than claiming strict causal attribution.
5. **Incomplete implementation of certain provisions:** Some elements, such as the full deployment of EUDAMED (and its mandatory use) and post-market data flows, are still under

development. The evaluation can therefore only assess early evidence of their effects. Other provisions were not assessed as part of the evaluation scope e.g. those not yet implemented.

A key difficulty is the **limited availability of reliable quantitative data** despite extensive consultation. Important data gaps in the overall baseline include (but are not limited to), the number of devices and economic operators on the Union market, a complete number of certificates and device safety incidents.

- Economic operators and notified bodies surveys provide averages by certificate type, device class (in some cases), and company size, but these do not reflect the diversity of experiences, especially for niche, orphan or in-house devices whose costs were not directly captured under these surveys.
- Qualitative inputs from the Call for Evidence and position papers highlight issues such as administrative duplication and delays in Eudamed, disproportionate costs for SMEs, but they lack quantitative estimates of time spent on duplication or on cost proportion.
- Workshops, interviews and case studies provided valuable insights but not representative figures.
- Methodological challenges included inconsistent interpretation of questions, missing values, and confidentiality concerns that limited data sharing.
- In addition, there was **no credible baseline measurement** against which to compare the observed costs.

As a result, survey figures should be treated as indicative ranges rather than precise measurements. Triangulation across sources improves robustness but cannot resolve inconsistencies. The evaluation therefore places greater weight on qualitative evidence, which consistently points to structural cost increases, administrative duplication, and disproportionate impacts on SMEs. At the same time, it underlines the need for better cost data collection in future monitoring.

More details on the data gaps related to the effectiveness criteria is available in the scoring tables (see *Annex VI*).

Mitigating measures included:

- Triangulation of findings across the main evidence sources to confirm broad consistency and highlight any divergences;
- Basic plausibility checks of quantitative results to identify outlier values or clear inconsistencies;
- Explicit acknowledgement of data gaps and careful, proportionate interpretation where evidence was incomplete;
- Use of expert judgement to contextualise findings and ensure balanced conclusions. These safeguards ensured that findings remained credible and proportionate to the available evidence.

5. Uncertainty and robustness of results

The evaluation explicitly accounted for uncertainty at each analytical stage, following *Tool #65*. Sources of uncertainty were categorised as (a) data-related, (b) methodological, and (c) contextual.

- **Data-related uncertainty** stems from incomplete or inconsistent datasets, especially for cost indicators and country-level variations.
- **Methodological uncertainty** arises from the combination of quantitative and qualitative evidence, which requires interpretation.
- **Contextual uncertainty** reflects the dynamic implementation environment and evolving guidance under the Regulations.

The evaluation did not attempt to quantify uncertainty numerically. Instead, qualitative considerations were used to judge the relative strength of evidence. Where several sources pointed in the same direction, findings were treated as broadly robust; where evidence was limited or divergent, results were interpreted with caution and described as indicative.

6. Quality assurance and reliability of the evidence base

Quality assurance followed the standards of *Tool #49* ("Format of the evaluation report") and *Tool #4* ("Evidence-informed policymaking"). Key safeguards included:

- Consistency with Better Regulation principles: All analytical work adhered to the principles of evidence quality, transparency, coherence, and proportionality.
- Traceability of evidence: Each finding in the SWD is linked to specific sources and indicators within the evaluation matrix, ensuring transparency and auditability.
- Internal coordination and review: Draft analytical sections were reviewed across relevant Commission services to ensure factual accuracy, methodological soundness and alignment with the evaluation matrix.
- Documentation and reproducibility: All analytical steps, including data compilation and scoring, were documented to facilitate verification.

This multi-layered quality process ensured that analytical conclusions are supported by verifiable evidence and consistent interpretation.

Despite data gaps and ongoing implementation, the overall evidence base is assessed as moderately to highly reliable. Several factors support this assessment:

- Breadth of coverage: The evaluation combines inputs from virtually all categories of stakeholders involved in the MDR/IVDR framework.
- Diversity of methods: The inclusion of both quantitative and qualitative sources ensures that no single dataset drives conclusions.
- Cross-validation: Triangulation across independent evidence streams enhances credibility.
- Transparency: Limitations, assumptions and uncertainties are explicitly stated and considered in the interpretation of findings.

While parts of the evidence base remain incomplete and certain data are still being collected as implementation progresses, the consistency of several key trends across independent sources provides a reasonable degree of confidence in the main findings. At the same time, some results should be interpreted with caution, particularly where data gaps persist or where the effects of the Regulations are still unfolding. Overall, the evaluation findings can be considered broadly reliable within the parameters of a complex and evolving regulatory environment.

ANNEX III. EVALUATION MATRIX AND, WHERE RELEVANT, DETAILS ON ANSWERS TO THE EVALUATION QUESTIONS (BY CRITERION)

For detailed answers to the evaluation questions related to the effectiveness criteria, see *Annex VI*. For the description of consultation activities referred to under 'data source', please refer to *Annex V*. For other terms, refer to the legend in *Annex VI*.

Evaluation question	***Judgment criteria***	***Indicator***	***Data source***	***Type of assessment***
Effectiveness				
*(1) How successful have the MDR and IVDR been in contributing to **its general objectives** in terms of:* *(a) ensuring a **high level of protection** of health for patients and users?* *(b) ensuring a smooth functioning of the **internal market** as regards medical devices?* *(c) supporting **competitiveness and innovation** in the sector, taking into account*	*-MDs and IVDs placed on the market are safe and performant.* *-Availability of safe devices on the Union market is maintained or improving across key categories.* *-Devices target specific needs of patients and target patient groups.* *-Improved protection of health of patients and users.* *-Even playing field across the EU for businesses* *-Increased level of innovation/ competitiveness.* *-EU market for placing innovations or research purposes.*	**Legal certainty** -Number of legal disputes -Experience/perception in implementation. -Number of disputes between manufacturers and notified bodies on device classification -Average duration of Helsinki procedure (MD/IVD)	**Legal certainty** -NCA survey - MDCG guidance documents (EC website), Study on governance, PC, CFE, position papers, Reality check workshop with manufacturers, EC internal sources	*quantitative and qualitative assessment*
		Transparency -Extent of public availability of device information via traceability mechanisms, EUDAMED and reports such as Publication of documents: SSCPs, summary monitoring reports);	**Transparency** - EUDAMED - PC, CFE, position papers	*quantitative and qualitative assessment*

specificities of SMEs? (d)*ensuring a high level of* ***transparency*** *on medical devices for all actors and citizens?*	*-Increased level of transparency of information on devices.* *-Traceability and lifecycle monitoring of devices are ensured across the EU.*	-stakeholder experience and satisfaction with access to device information.		
		Trust -Stakeholders' trust in regulatory system	**Trust** PC, CFE, position papers	*qualitative assessment*
		Notified bodies (NBs) -Number of NBs designated, code coverage in designation scope. -Average time for NB designation -Number of meetings and MDCG guidance documents on NBs oversight and coordination	**Notified bodies (NBs)** -NANDO information system (EC website), MDCG guidance documents (EC website) - Data from NB designation process, (EC internal sources), NCA survey	*quantitative and qualitative assessment*

		Conformity assessments -Resources of NBs and-time for issuance of new certificates -Stakeholders' perceptions of predictability and proportionality of procedures.	**Conformity assessments** - NB survey, GOG study - PC, CFE, position papers	*quantitative and qualitative assessment*

		Clinical evidence - Number of clinical investigation applications -Experience of NBs on CERs and PERs -Number of CECP/PECP submissions and expert panel opinions -Stakeholder perceptions	**Clinical evidence** - NCA survey, EO survey, NB survey, Workshop with MDCG stakeholders, Reality check workshop with manufacturers - PC, CFE, position papers	*quantitative and qualitative assessment*

		Competitiveness and innovation -Value and growth rate of the European medical devices market -Number and growth rate of patents from the EU -EU export position -Recognition of the CE marking in other jurisdictions -EU's international cooperation -Number of bi-lateral operational agreements -Number of certificates issued through combined audits (MDSAP & MDR/IVDR) -Stakeholders' perceptions of Union market attractiveness for innovation. -Experience in uniform application of requirements and national practices -Number of applications and issued certificates	**Competitiveness and innovation** -MedTech Europe facts & figures 2025 - European Patents Office -PC -IMDRF website, EC internal sources -NB survey -PC, CfE, position papers, study on governance -PC, CfE, position papers -GOG study	

		-Number of notification of interruptions or discontinuations of devices -Stakeholders' perception on shortages and on related patient needs, including orphan devices -Experience of stakeholders on requirements for in-house devices	-EC internal sources -PC, CfE, position papers, reality check with healthcare professionals, users, patients	

		(Post-)Market surveillance and vigilance -Stakeholders perception -Trend in number of serious incident reports, (MIR), periodic safety reports (PSR), field safety corrective action. -Stakeholders' perceptions perception of effectiveness and proportionality of PMS/vigilance requirements -Number of proactive and reactive on-site inspection and products controls -Participation of NCAs in EU coordination on vigilance and market surveillance (e.g. coordination exchanges, task forces or obligations etc).	**(Post-)Market surveillance and vigilance** -reality check with healthcare professionals, users, patients -PC, EC internal sources, NCA survey -PC, CFE, position papers -EC internal sources, NCA survey	

		Simplification -Stakeholders' experience and views on the governance -Stakeholders' perception of predictability, proportionality, and administrative burden. - Experience with use of digital tools and EUDAMED	**Simplification** - CFE, position papers, study on governance - PC, CFE, position papers, study on governance, Reality check workshop with manufacturers	

*(2) What **internal and external factors** have contributed to or hindered the progress towards the objectives of the MDR and IVDR? And how?*		-Impact of COVID-19 -Effectiveness & efficiency of governance structure	- EC internal sources, MDCG guidance documents on COVID-19 (EC website) - Study on governance	*quantitative and qualitative assessment*
*(3) (a) To what extent have the **objectives been achieved** and to what extent can they still be achieved?* *(b) Considering the current regulatory framework and ways of implementing it, can they be achieved by the end of the transition period?*	*-Objectives are considered achieved when evidence shows clear progress towards improved safety, transparency, legal certainty, and a functioning internal market.* *-The stage of implementation of the Regulation shows that the objectives related to patient safety, transparency and traceability can be achieved by the end of the transition period.*	/	/	*qualitative assessment*
*(4) To what extent are the **extensions of the transition periods and other introduced***	*-Sufficient transition periods for all stakeholders to implement the Regulations in time.*	Stakeholder's experience with transition periods	- position papers	*qualitative assessment*

legislative changes *addressing the concerns identified at the early stages of the implementation of the MDR/IVDR?*	*-Problems identified have been addressed and ensure that the objectives of the Regulations can be met.*			
(5) Have any ***unexpected or unintended effects*** *occurred? To what extent have they contributed or hindered progress towards the objectives? What can explain these effects?*	*-A limited number of unexpected or unintended negative effects have occurred.*	Availability of devices Competitiveness/innovation	- GOG survey, PC, CFE, position papers - EO survey, GOG survey, PC, CFE, position papers	*quantitative and qualitative assessment*
Efficiency				
(6) (a) What is the division of ***costs and benefits*** *for different stakeholders?* *(b) Are they* ***distributed*** *as expected and if not, why?*	*-Costs and benefits are proportionate to the roles and responsibilities of each stakeholder group (manufacturers, NBs, NCAs, health institutions, Commission).* *- Benefits are materialising as intended for patients and healthcare systems, while costs remain proportionate to stakeholders' roles and obligations*	*See Annex IV* Manufacturers: average certification costs; cost of pre-market clinical evaluations/performance studies; post-market surveillance costs.	- NB survey, EO survey, reality check with manufacturers, CfE, PC	*quantitative and qualitative assessment*

	-Industry operate in a clearer regulatory framework but face increased costs. .	NBs: designation and maintenance costs; resources for audits and assessments. NCAs: staff and IT costs; participation in EU level vigilance and coordination activities. Commission / EU governance: EUDAMED development and maintenance costs; MDCG coordination workload; EMA Patients / health systems: stakeholder perceptions of device safety, quality, and availability.	- NB survey, EO survey - NCA survey -EC website, EU4Health Programmes, EMA survey - PC, CFE, position papers, Reality check workshop with healthcare professionals, users and patients	
*(7) Are the **costs** of the MDR/IVDR **justified**, given the results that are being achieved?*	*-Overall costs are reasonable in relation to the benefits achieved in terms of patient safety, quality, and public health protection* *-Efficiency gains and long-term benefits (e.g. harmonisation, trust,*	Trends in serious incidents and vigilance reports (proxy for safety gains). Stakeholder perception of proportionality between costs and benefits.	- PC, EC internal sources, NCA survey - PC, CFE, position papers	*quantitative and qualitative assessment*

	transparency) outweigh short-term implementation costs.	Market growth or stability despite higher compliance costs. Level of harmonisation and predictability achieved (number of NBs designated, guidance issued).	- MedTech Europe facts & figures - NANDO information system, EC website, PC, CFE, position papers	
*(8) Is there a **potential** to **reduce the compliance costs** and/or the administrative burden without compromising the objectives of the MDR and IDVR?*	*-The Regulations can be simplified.*	Stakeholder perception of administrative burden and duplication of reporting. Experience with digitalisation and EUDAMED use. Number of overlapping or redundant requirements identified.	- PC, CFE, position papers - PC, CFE, position papers - Expert study on coherence, EC internal sources	
Relevance				
*(9) (a) How well do the objectives of the MDR and IVDR **still correspond** to the **needs** within the EU?*	*-Today's needs for safe, performant and innovative medical devices in the EU are addressed.*	Alignment of objectives with stakeholders' current needs.	- CFE, position papers, Reality check workshop with healthcare professionals, users and patients	*qualitative assessment*

(b) How effectively do the MDR and IVDR address ***emerging health challenges*** *and* ***evolving patient needs*** *within the EU?* *(c) How flexible are the MDR and IVDR to adapt to the* ***technological or scientific progress*** *and* ***innovation*** *in the sector that already occurred?*	*-Emerging health challenges and evolving patient needs are addressed.* *-The Regulations provide a flexible framework allowing the regulation of technological/ scientific progress and innovative devices to reach the market.* The framework remains suitable to respond to emerging health challenges and new patient needs.	Stakeholder perception of continued relevance of MDR/IVDR objectives. Stakeholder perception of capacity to accommodate evolving clinical and patient needs. Stakeholder perception of regulatory adaptability and predictability for innovation.	- Study on governance, PC, CFE, position papers - CFE, position papers - Study on governance, PC, CFE, position papers	
(10)To what extent are the ***processes and mechanisms*** *of the MDR and IVDR still relevant in view of the objectives?*	*Core processes (designation of NBs, conformity assessment, PMS, vigilance) remain appropriate to achieve the objectives of the Regulations.*	Stakeholder feedback on continued suitability of key processes.	- PC, CFE, position papers	
Coherence				
(11)To what extent are the various elements of MDR and IVDR ***coherent with one another****?*	*The elements of the MDR and IVDR are coherent.*	-Evidence of alignment between provisions of MDR and IVDR, within the Regulations and MDR/IVDR requirements and their accompanying Annexes	- EC internal sources, Expert study on coherence, PC, CFE, position papers	*qualitative assessment*

		-Stakeholder perception of internal coherence		
*(12)To what extent are the MDR and IVDR coherent with **other EU** (and, if applicable, national) **interventions** that have similar objectives?*	*The MDR and IVDR are overall coherent with other EU interventions.*	-Evidence and stakeholder perception of alignment between MDR/IVDR and other Union Regulations (e.g. AI Act, EHDS, packaging/packaging waste etc.	- EC internal sources, Expert study on coherence, PC, CFE, position papers	
*(13)To what extent are the MDR and IVDR coherent with (current) wider **EU policies and priorities?***	*The MDR and IVDR are coherent with wider EU policies and priorities.*	-Evidence of alignment of MDR/IVDR with wider EU policies	-EC internal sources	
*(14)To what extent are the MDR and IVDR coherent with **international** obligations and policies?*	*The MDR and IVDR are overall coherent with international obligations and policies.*	-Evidence of alignment of MDR/IVDR with international obligations and policies	-EC internal sources	
EU added value				
(15)To what extent were the objectives of the policy better achieved by reason of scale or effects of that action than by the	*-Benefits resulting from the Regulations compared to what would have been expected with Member States acting alone.*	-Reduction in divergent national requirements or guidance. -Stakeholder perception of predictability and uniformity of rules.	- PC, CFE, position papers	*qualitative assessment*

Member States acting alone?		-Functioning of EU-level structures (MDCG, joint assessments, vigilance coordination). Number of common guidance documents and joint actions. -Stakeholder perception of added value of EU-level oversight compared to national-only regulation.	- Study on governance - EC website - PC, CFE, position papers	

ANNEX IV. OVERVIEW OF BENEFITS AND COSTS, TABLE ON SIMPLIFICATION AND BURDEN REDUCTION

Table 1. Overview of costs and benefits identified in the evaluation									
		Citizens/Consumers		Businesses		Administrations		Notified Bodies	
		Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
[Cost or Benefit description]:									
Costs:									
Direct compliance costs (adjustment costs, administrative costs, regulatory charges)	**Type:** Choose **one-off or recurrent**			**MDR** (one-off and recurrent): -Clinical evaluation €30 000 – €250 000 per study. Recurrent for each new device or major change. -Certification fees: QMS Annex IX (I+III) €641 878 → €882 988; QMS Annex XI (Part A) €100 000 → €188 524; Product Annex IX (II) €616 981 → €385 617; maintenance €48 503 – €73 244. Recurrent for renewals and annual maintenance. -Importers €32 860 / year; Distributors €33 496 / year (after outlier exclusion).	No costs could be captured on clinical investigations and performance studies, which tend to exceed costs for clinical evaluations. Data collected across different sources did not allow to accurately determine cost variation across certificates for different device risk classes nor per manufacturer size. Costs such as NB fees and resources for clinical evaluation or performance studies can be estimated, but coverage is uneven.		**NCA**: NB designation via joint assessments and oversight of NBs; Pre-market assessment, 37-156 hours per clinical evaluation/performance study; IT investments; staff recruitment and training activities, including for vigilance & market surveillance; EU coordination activities (One-off setup and recurrent operating costs). **Perception**: NCAs report increased administrative burden but acknowledge improved		Costs for designation process, staffing, training, IT, and coordination.

				Mostly recurrent administrative costs. **IVDR** (one-off and recurrent): -Performance evaluation €23 000 – €70 000 per study. -QMS Annex IX (I+III): issuance €1 205 458 (inc. €5.5 m multi-device outlier); excluding outlier €131 823; "last" €388 918; maintenance €121 250. -Product Annex IX (II): issuance €89 750 → last €109 700; change-management €13 563. **Perception:** Strong consensus among Economic operators and SMEs that costs are high and disproportionate to firm size; Notified bodies bottlenecks and delays seen as major indirect drivers of cost but problem is decreasing. Benefits expected in legal certainty	Less data received across IVDR certificate types, meaning more limited analysis possible.		coordination and data quality. **EU level:** EUDAMED development and maintenance (one-off and recurrent); MDCG coordination and expert panel support (Commission budget lines). **Perception**: High initial IT investment but broad agreement on long-term value for harmonisation and transparency.		

				and market trust once system stabilises.					
Enforcement costs: (costs associated with activities linked to the implementation of an initiative such as monitoring, inspections and adjudication/litigation)							-Enforcement activities resulting from the monitoring of notified bodies, vigilance (assessment of report and follow-up) and market surveillance activities (e.g. inspections, evaluations and measures). **Perception**: For monitoring of notified bodies, seen as necessary for quality control but resource-intensive for smaller authorities.		-Staff training and audit costs. (One-off for designation; recurrent for oversight). -Workload linked to ongoing applications and (recurrent) surveillance of manufacturers post-certification **Perception:** Variation in NB capacity, constraints at start of implementation now easing.
Indirect costs (indirect compliance costs or other indirect costs such as transaction costs)			Delayed access to some innovative or niche devices; reported shortages (recurrent) **Perception:** Patients and professionals acknowledge safety benefits but		-**MDR**: Certification timelines 6 – 18 months (often up to 24 months); Portfolio reductions for low-volume devices; SME opportunity		-Transition management from Directives to Regulations and associated legislative amendments; coordination burden across MS and EU		NB hassle costs/waiting times for designation ((~1 500 days per designation) ; quality of manufacturer applications can impact

			criticise reduced availability and delays		costs (one off and recurrent) -**IVDR**: Higher relative burden for in house devices and SMEs; High compliance burden for laboratories and health institutions, with many reporting risk of discontinuing in-house devices under current IVDR requirements (one off and recurrent) **Perception**: Stakeholders see indirect effects as the most pressing issue for availability and innovation - Delayed market access, portfolio withdrawals, and administrative burdens—are harder to quantify but consistently reported as substantial, especially for SMEs, niche manufacturers, and small laboratories.		structures (recurrent) **Perception**: Short-term inefficiency accepted as transitional.		certification timelines. **Perception**: Improving as processes stabilise.
Benefits:									

									.
Direct benefits (such as improved well being: changes in pollution levels, safety, health, employment; market efficiency)			-Improving safety and device quality through stricter clinical/ performance evidence and post-market surveillance (recurrent) -Increasing transparency and traceability via UDI and EUDAMED (modules progressively operational) (recurrent). **Perception:** Expected safety gains among patients and users; offset by concerns about device availability.		-Harmonised rules and predictable EU framework expected to reduce legal uncertainty; increased safety rules enhance CE mark credibility and reputation benefits for exporters. (recurrent) **Perception**: Businesses acknowledge long-term benefits but say they are yet to materialise due to implementation delays.	-Enhanced market surveillance and coordinated vigilance (8× increase in product controls; +25 % compliance exchanges). **Perception**: Authorities better equipped for monitoring with empowerment & common EU platforms and tools for safety and traceability gains.	**EU level** EU-wide improved oversight and knowledge-sharing through MDCG and scientific oversight of devices strengthened. via expert panels (recurrent) **Perception:** Positive impact on consistency and global standing of EU system.		Higher revenues and efficiency gains. This illustrates a core trade-off: costs borne by manufacturers translate into revenue for NBs.
Indirect benefits (such as wider economic benefits, macroeconomic benefits, social impacts, environmental impacts)			-Higher public trust and informed choice expected through better access to device information (recurrent)		-Long-term competitiveness and export potential from global trust and recognition of CE mark; incentive for quality innovation once predictability improves. (recurrent) **Perception:** Most industry actors agree benefits will		Efficiency gains from shared IT systems (EUDAMED) and harmonised guidance documents (MDCG). (recurrent) **Perception**: Viewed as major administrative simplification in		

					materialise once backlogs clear.		the medium term. **EU level** Improved international regulatory cooperation and convergence (mutual recognition dialogues) (recurrent). **Perception**: Helps EU get a leadership position in global medical device regulation		

TABLE 2: Simplification and burden reduction (savings already achieved)								
	Citizens/Consumers/Workers		Businesses		Administrations		Notified bodies	
	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitati ve	Comment
Compliance cost savings								
Type: One-off / recurrent	N/A	N/A		Reduced costs of having to comply with different market entry requirements and multiple national databases from Member States (recurrent)				N/A
Compliance cost savings								
						Reduced costs from having to set-up and maintain regulatory databases at national level (in some MS so far), due to set-		

						up of EU-level database (Eudamed)		
PART II: II <u>Potential</u> simplification and burden reduction (savings)								
	Citizens/Consumers/Workers		Businesses		Administrations		Notified Bodies	
	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Compliance costs								
Type: One-off / recurrent	N/A	N/A		Streamlining reporting obligations and overlaps (e.g. pre-market (SSCP) and post-market, PSUR, etc). (recurrent) More tailored requirements for low and medium risk (e.g. clinical evidence) devices and for		National: Streamlined processes for Notified Body designation More centralised oversight of NBs Streamlined and clearer coordination at EU-		Reduce overlapping assessments of reports (e.g. vigilance)

				in-house devices (recurrent) Predictability of the system could be enhanced by allowing early dialogue with notified bodies, ensuring clear certification timelines, and addressing resource-intensive and lengthy consultation procedures (recurrent) Reduced fees charged by NBs to micro and small enterprises (one-off & recurrent). Flexible regulatory		level (i.e. governance : MDCG and sub-groups)		

				pathways for innovative and niche devices (orphan, small or vulnerable populations) (recurrent) Increased digitalisation of regulatory compliance such as via expanded electronic instructions for use (e-IFUs), electronic labelling, and the development of electronic submission systems (recurrent).				

Table 1 **Synthesis of the cost-benefit analysis per stakeholder category** (See also *section 4.1.2* of the Evaluation Report)

Impact		Weight / Importance	Score (--/– /0/+/++)	Explanation (qualitative summary)
Manufacturers	Costs	High	– –	Substantial compliance costs: clinical /performance evaluations, technical documentation, NB fees, post-market surveillance. Strongly disproportionate for SMEs and low-risk devices.
	Benefits	Medium	+	Potential for greater legal certainty, reputational gains, better market access through harmonisation. Benefits recognised but not yet fully materialised.
Importers / Distributors	Costs	Low	–	Mainly administrative: EUDAMED registration, CE verification, documentation flows. Felt most heavily by SMEs.
	Benefits	Low	0	Benefits are neutral, no direct benefits reported.
Notified Bodies	Costs	Medium	–	High costs for designation, staff recruitment, training, IT, and coordination.
	Benefits	Medium	++	Significant increase in revenues from certification activities; specialisation creates efficiency gains.
NCAs	Costs	Medium	–	Higher HR needs, IT investment (especially EUDAMED, vigilance), participation in MDCG and joint assessments. Particularly heavy for smaller NCAs.
	Benefits	Medium	+	Stronger market surveillance role, legal clarity, improved coordination across Member States.
H. Health Providers	Costs	Medium	–	Administrative burden for health institutions for in-house devices, delays in access to innovative devices, compliance costs for IVDR.
	Benefits	Medium	+	Despite the costs, improved safety assurance and clinical evidence requirements, along with anticipated gains in transparency through EUDAMED.
Patients / Users	Costs	Medium	–	Indirect: reduced availability of niche/innovative devices, delays in access.
	Benefits	High	+	Improving safety, higher device quality, transparency and trust in CE marking. Benefits not fully realised due to on-going implementation, potential for increased score.
EU-level governance	Costs	Medium	–	Development and maintenance of EUDAMED, staff resources for MDCG coordination and joint assessments (EC), and consultation procedure handling (EMA).
	Benefits	Medium	+	Harmonised Union market, stronger global positioning, reduced duplication of national frameworks.

ANNEX V. STAKEHOLDERS CONSULTATION - SYNOPSIS REPORT

1. INTRODUCTION: OBJECTIVES, CONSULTATION ACTIVITIES, METHODOLOGY

1.1. Objectives of the consultation

The Commission held various consultations for a targeted evaluation of the Regulations. The aim of this consultation was to collect evidence and perspectives of all stakeholder groups on the performance of the legislation, focusing on the impact of the legislation on the availability of devices, including devices for small populations ('orphan' and 'niche'), as well as the development of innovative devices, costs and administrative burdens arising from the legislation, and benefits of the legislation.

This synopsis report provides an overview of the consultation activities undertaken, and a description of the results.

This synopsis report is largely based on the synopsis report prepared by a contractor in the context of the analysis of some evidence collected[270].

1.2. Overview of consultation activities

The **public consultation** (PC) (12 December 2024 to 21 March 2025) aimed to obtain feedback on the effectiveness, efficiency, relevance, coherence and EU added value of the MDR and IVDR from their implementation in 2017 to 2024. The consultation asked for views on the effectiveness of how the MDR and IVDR are implemented, focusing on the protection of health for patients and users, transparency and traceability of medical devices on the Union market, the functioning of the internal market for medical devices, the competitiveness and innovation of the medical device sector in the EU, and the efficiency, relevance and coherence of the EU rules on medical devices. In this context, a specific set of questions was available for citizens and organisations representing patients. The rest of the questionnaire was structured around two sections, one applicable to medical devices (MDs) and one applicable to *in vitro* diagnostic medical devices (IVDs). The PC was accompanied, during the same period, by a **Call for Evidence** (CfE) allowing interested parties to provide feedback.

[270] See note 25, pg 7.

Information was also collected through **targeted surveys** conducted for the following groups:

- National competent authorities (December 2024 – March 2025),
- Notified bodies (November 2024 – January 2025),
- Economic operators (EOs) (January 2025 – March 2025)
- European Medicines Agency (EMA) (January 2025 – March 2025),

In addition, views from healthcare professionals were extracted from a survey conducted by GOG[271].

Furthermore, two **reality check workshops** have been organised. A workshop with manufacturers on costs was organised in February 2025, and a workshop with healthcare professionals, patients and users on costs and benefits was organised in March 2025.

Consultation activities also took place in the context of the **MDCG**, including a dedicated **workshop** in February. An **information session** on the evaluation has been organised by the European Commission with international partners to communicate on the ongoing work (May 2025).

Additional analysis was conducted on **position papers** submitted as ad-hoc contributions through the '**Study** supporting the targeted evaluation of the MDR and IVDR'.

Furthermore, in the context of the '**Study on Regulatory Governance** and Innovation in the field of Medical Devices'[272], consultation activities including one survey (open from 12 December 2023 until 5 February 2024, with a total of 470 responses considered for the analysis), **interviews**, as well as **four**

[271] European Commission website – *Study supporting the monitoring of availability of medical devices on the EU market*. *The study has been contracted to a consortium led by the Austrian National Public Health Institute (Gesundheit Österreich GmbH/GÖG), in collaboration with Areté and Civic Consulting*, Survey on the Health Service Providers.

[272] See note 91, pg 18.

thematic workshops and **three additional stakeholder consultation workshops.** In this context, one of the four thematic workshops was organised **specifically with representatives of SMEs (with 28 organisations attending).**

1.3.Stakeholders mapping

These activities aimed to target all interested parties, including EU institutions and agencies, Member States competent authorities, economic operators (both SMEs and large manufacturers), notified bodies, EU Authorised Representatives, healthcare professionals or institutions, importers and distributors of medical devices in the EU, regulatory affairs experts, system/procedure pack producers, international intergovernmental organisations, civil society organisations, clinical investigators, ethics committees, the general public, patients and consumers, independent experts from academic and research institutes, and non-EU/EEA countries (see detailed stakeholder mapping in *Annex VIII*).

1.4.Methodology

With regards to the Public Consultation and Call for Evidence, the European Commission has performed the analysis of potential campaigns, duplicates and respect of feedback rules.

In the context of the 'Study supporting the targeted evaluation of the MDR and IVDR', the contractor analysed part of the Public consultation questionnaire, the Call for Evidence, the surveys on economic operators, national competent authorities and notified bodies, as well as the position papers. For these, two main methodologies were applied: one for the surveys (the public consultation, economic operators survey, national competent authorities survey, notified body survey), and another for the analyses of the Call for Evidence and of the position papers. While both followed a consistent methodology, adaptations were executed to fit the specific type and format of the data.

Data of the **PC and surveys** were reviewed, cleaned, and reformatted as needed, with considerations and potential data limitations noted throughout. Survey questions were first classified by type, and an appropriate analysis method was assigned to each. All responses were then analysed accordingly per question using Microsoft Excel while taking potential limitations into consideration.

One limitation of the analyses using surveys was a lack of consistency and clarity in the treatment of missing data. In certain instances, respondents who were unable or unwilling to provide figures entered a value of **0**. This approach created ambiguity, as the entry could be interpreted as representing an actual value of zero (e.g., 0 EUR), when in fact it reflected a deliberate decision not to disclose data. In another survey, respondents were instructed to leave

fields blank if the requested information could not be retrieved. It is not possible to determine with certainty whether a blank field indicates the unavailability of data or simply a skipped question. Another limitation of the data was insufficient response numbers to conduct comparisons across sub-groups of respondents.

The **position papers and the Call for Evidence** were also analysed in a similar fashion. Position papers (including a number of literature articles) and Call for Evidence inputs (survey text box responses and attached documents) were first reviewed and cleaned (e.g. removing duplicates of position papers or Call for Evidence attachments sent by the Commission). The text retrieved from the position papers and Call for Evidence was then processed using the AI Policy Concierge (AIPC), a tool developed by Technopolis' Data Science Unit to apply generative AI in policy analysis. The AIPC securely applies a large language model and allows for customised prompts; in this case, to extract summaries, authors, affiliations, publication dates, and thematic relevance per document including examples (for position papers) or per entry (for Call for Evidence). The extracted text was then analysed by theme and stakeholder group. Stakeholder identification differed between Call for Evidence and position papers: the Call for Evidence included stakeholder details submitted as part of their Call for Evidence response (standard categories included in EU Survey/Have Your Say), while the position papers required stakeholder groupings to be extracted from author affiliations. The AIPC analysis was complemented by sample checks to ensure the quality and accuracy of the output produced.

The use of an AI tool in this application comes with both benefits and limitations. Its main advantage lies in its ability to quickly process and analyse large volumes of text, which is crucial given the number of responses and documents involved. It also efficiently retrieves key information such as authors, affiliations, publication dates, and develops summaries accurately. However, the following limitations are to be considered:

- The first limitation is the **high sensitivity with linking themes** when the AIPC is applied to analyse feedback; a theme that is briefly mentioned but not deeply discussed is considered as a linkage to a theme. A sample of 10 to 15 documents was reviewed prior to each iteration/run of the AIPC to verify interpretations and assess the output. The reviews showed that while the AIPC made accurate links, it also included indirect and/or weaker links to the themes. No links were found to be fully incorrect, but this sensitivity should be kept in mind when interpreting the results.

- The second limitation is that **language models have inherent challenges in counting**[273], which affects the counting of stakeholder perspectives with the AIPC. The model may over- or under-count by a few responses. To validate the counts, a smaller sample of responses was manually reviewed. The findings were consistent in broad terms, though some results may remain open to interpretation— similar to manual (or 'human') analysis.
- The third limitation is that **language models do not generate identical output with each run**. Because multiple feedback rounds required refining and several iterations of the AIPC analysis, there may be small variations between runs. Despite this, the overall results were largely consistent, allowing to build on previous versions.

2. The other consultation activities (**i.e. the remaining surveys, the workshops and the additional Public Consultation questions) were analysed separately. RESPONDENTS TO THE CONSULTATION PROCESS**

2.1. General overview

Table 1 outlines stakeholder groups directly, indirectly, or potentially affected by the MDR and IVDR. A mix of medium/high, medium/medium, low/high and low/medium stakeholders have also provided data thereby maximising the breadth of the influences and interests taken into account. The PC and CFE are public consultations open to all stakeholders and citizens. Table 1presents the stakeholder groups who have participated Clinical investigators, ethics committees, and other international associations were identified but not consulted).[274]

[273] Thomas Ball, Shuo Chen and Cormac Herley (2024). Can We Count on LLMs? The Fixed-Effect Fallacy and Claims of GPT-4 Capabilities. Retrieved from: https://arxiv.org/html/2409.07638v2

[274] These groups were not included as selectable options in the user type section of the public consultation or call for evidence there are limitation in identifying these groups. This is because they were difficult to reach.

Table 1 Stakeholders consulted[275]

Stakeholder group	Influence	Interest	Consultation method						
			PC	CfE	Surveys	PP	MDCG meetings	Reality check workshops	Info session
European Commission and EU bodies, including the EMA	High	High		■	■	■	■		
EU MS competent authorities	High	High	■		■	■	■	■	
Large European manufacturers and/or associations	High	High	■	■	■	■	■	■	
Notified bodies	High	High	■	■	■	■	■		
EU Authorised Representatives	Medium	High		■	■	■	■		
Healthcare professionals and institutions, and/or associations	Medium	High	■	■		■	■	■	
European SMEs and start-ups	Medium	High	■	■	■	■	■	■	
Importers and distributors of medical devices in the EU, and/or associations	Medium	High			■	■	■		
Regulatory affairs experts, and/or associations	Medium	High		■		■	■		
System/procedure pack producers (SPPP) and/or associations	Medium	High			■		■		
International intergovernmental organisations and other international associations	Medium	Medium					■		
Large non-EU manufacturers	Medium	Medium	■		■				
Civil society organisations (CSOs)	Low	High	■						
Clinical investigators	Low	High							
Digital health, software and AI-tech developers	Low	High				■			
Ethics committees	Low	High							

[275] This table does not include activities under the governance study.

Stakeholder group	**Influence**	**Interest**	**Consultation method**						
			PC	CfE	Surveys	PP	MDCG meetings	Reality check workshops	Info session
General public, patients and consumers, and/or associations	Low	High	■			■	■	■	
Non-EU SMEs and start ups	Low	High	■		■	■			
Independent experts from academic and research institutes	Low	Medium	■	■		■			
Non-EU/EEA authorities	Low		■		■				■

More details on some of the consultation activities are provided in the sub-sequent sections.

2.2. Public consultation (PC)

Detailed information on the public consultation results and the Factual Summary Report can be found on the Have Your Say webpage[276]. No duplicates or campaigns were identified, and feedback rules were respected. All 332 responses as well as 51 attachments (out of 52) were included in the analysis.

86% of responses came from 16 EU Member States (287/332). The majority of replies (42% or 145) were submitted by individuals in Germany and France. In contrast, 14% of responses were from respondents in non-EU countries (United States (23); Switzerland (10); United Kingdom (5); Australia (2); China (1); Türkiye (1); Liechtenstein (1); Brazil (1); Canada (1)).

The number of responses per stakeholder type is shown in Figure 1[277]. **As part of the economic operators, a majority of responses were from small and medium-sized enterprises** (43 were **medium** (50-250 employees); 32 were **small** (10-50 employees)**;** 17 were **micro** (less than 10 employees)) in comparison to 59 responses from large-sized companies (250+ employees).

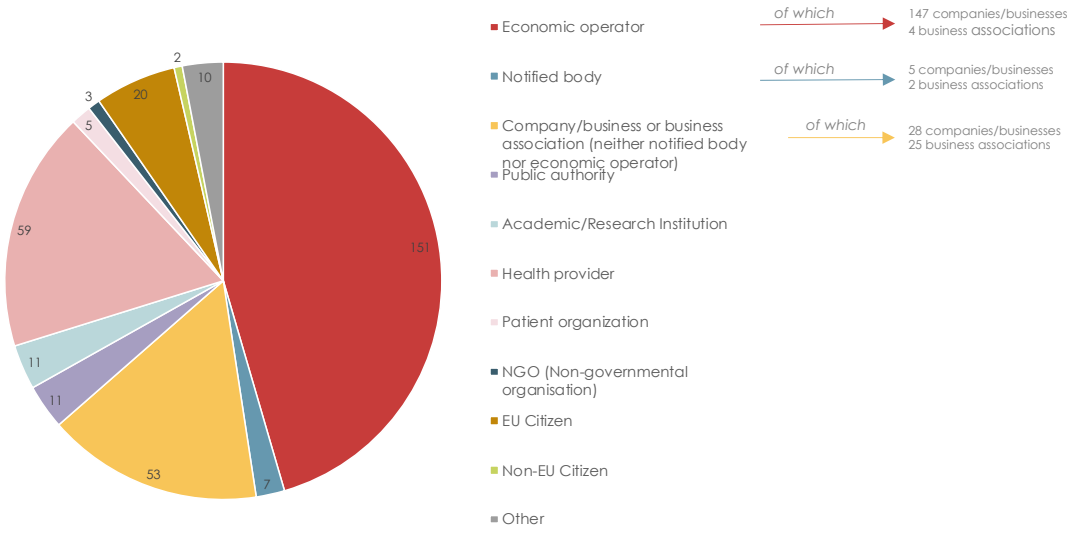
The majority of public authorities (n=11) were **national authorities** (n = 8). In addition, two **regional** and **one local authority** also contributed to the PC. No duplicates or campaigns were identified, and feedback rules were respected. All 332 responses as well as 51 attachments (out of 52) were included in the analysis.

Note that EU/non-EU citizens responded to a different, more limited, set of questions than other stakeholder types. In this synopsis report, unless otherwise specified, findings from the PC refer to findings from all stakeholder types *except* citizens.

[276] European Commission website, *public consultation – EU rules on medical devise and in vitro diagnostics – targeted evaluation*

[277] Note that three Notified Bodies who completed the survey did not identify themselves as such in the public consultation. As a result, they were classified under "Other", in line with their own self-identification, rather than being included in the Notified Bodies category.

Figure 1 Survey respondents by stakeholder type



When reporting PC results, the percentage of respondents who agreed or strongly agreed with each survey statement is shown. In other words, the share of people selecting agree/strongly agree is compared with all other options (neutral, disagree, strongly disagree, not applicable/don't know).

2.3. Call for Evidence

Detailed information on the Call for Evidence and all received feedback responses can be found on the European Commission Website[278]. A total of 584 feedback responses have been received, including both **survey text box responses and 186 attached documents**. During data cleaning:

- 6 responses were discarded for not complying with feedback rules.
- 4 duplicates were removed (organisations that submitted feedback twice).
- 1 campaign consisting of 13 entries was removed and analysed separately.
- 28 responses were merged into 9 because they were considered successive and complementary feedback.

This resulted in a final set of 542 feedback items, of which 168 included one or more attachments. In the study, the responses were analysed across **20 themes**, defined by the European Commission. Where this synopsis report refers to specific figures or percentages, these are calculated on the total number of feedback responses discussing a specific theme.

[278] European Commission website, *call for evidence* – *EU rules on medical devices and in vitro diagnostics – targeted evaluation*

For this reason, there are different denominators used throughout the analysis of the Call for Evidence. The denominator for a given figure or percentage is always provided.

The distribution of participating stakeholders is presented in Figure 2.

Figure 2 CFE respondents by stakeholder type

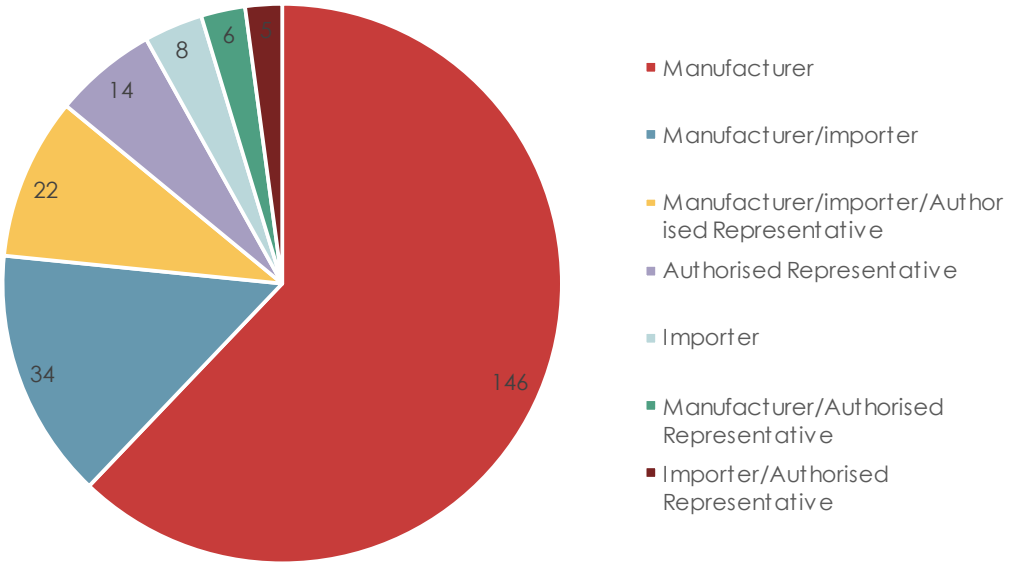
As part of the 206 responses from companies/businesses, around 80% were SMEs, whose contributions are reflected in the analysis.

2.4. Targeted surveys (TS)

National competent authorities: Responses were obtained from 18 competent authorities: 16 from EU Member States, 1 from an EEA country and one from a Customs Union country. Each Member State was permitted to provide one response only.

Economic operators (EOs): Responses were obtained from 254 EOs, 202/254 or 79.5% of which were EU-based EOs and 52/254 or 20.5% were based outside the EU. 235/254 or 92.5% of these EOs were registered in EUDAMED, and their stakeholder type as registered in EUDAMED is shown below:

Figure 3 Stakeholder type at EUDAMED registration



A majority of responses were received from small and medium-sized enterprises (SMEs) (174/254 or 68.5%), as well as 80/254 or 31.5% of the EOs that can be designated as large (250 or more employees). Of note, Medtech Europe reports that 90% of medical technology companies are SMEs in the EU[279], suggesting that SMEs were under-represented in the targeted survey sample. The average number of staff employed for regulatory compliance with MDR and IVDR counted in Full Time Equivalents (FTE) employed on 31/10/2024 is 20 for SMEs and 167 for large companies.

Notified Bodies (NBs): Responses were obtained from 50 notified bodies, of which the majority (37/50 or 74%) were designated under MDR only, a smaller proportion (12/50 or 24%) were designated under both the MDR and IVDR, and just one notified body was designated under IVDR only.

European Medicines Agency (EMA): One response was collected from the EMA.

Governance study: Information on the survey and interview respondents can be found in the published report.[280]

2.5. Ad hoc contributions: position papers (PP)

Both position papers and literature articles were received for analysis. Among the 211 position papers, 12 duplicates were identified, 7 files were submitted in formats incompatible with the analysis methods (such as image and message files), and one file was corrupted. In addition, a total of 26 literature articles were submitted, including 5 project deliverables and 13 publications from the CORE-MD consortium. The literature

[279] MedTech Europe website, *Facts and Figures 2024*.
[280] See note 91, page 18.

articles did not require cleaning. In total, 217 files were available for analysis. The majority of the materials date from recent years; 65 (30%) in 2025, 54 (25%) in 2024, 39 (18%) in 2023, 8 (4%) in 2022, 9 (4%) in 2021 and the remaining articles had been published between 2008 and 2020.

3. DISCUSSION OF RESULTS

3.1. Effectiveness

Just under half of the respondents to the PC agreed that the Regulations have contributed to **protecting the health of patients and have contributed to protecting the health of users** (MDR: 46% or 110/240 for patients and 40% or 95/240 for users; IVDR: 44% or 50/113 for patients and 35% or 40/113 for users)[281]. While there were some differences in percentages across stakeholder groups, no explicitly disagreeing views were observed across groups. Meaningful comparisons were difficult due to varying response numbers per stakeholder group; NBs, public authorities, and patient organisations appeared to view the MDR's effectiveness in protecting the health of patients and users more positively, but their low response rates limit data reliability. A small number of EU citizens responded to the public consultation, and they were slightly more positive about the effectiveness of MDR/IVDR in protecting health: 67% (14/21) agreed that MD/IVD are regulated in a way that contributes to a high level of health protection.

253 feedback responses to the CfE discussed the impact of the Regulations on patient health. 44.3% (112 entries[282]) of these responses discussed reduced patient access to medical devices, innovative treatments, or diagnostics, and the negative impact on care resulting from the MDR/IVDR. 30.8% (78 entries[283]), discussed how the increased administrative or financial burden did not result in clear patient benefits. Some stakeholders also raised the Regulations' failure to improve patient safety or create benefits for patients (89 entries[284], 35.1%). However, 29 entries[285] (11.5%) acknowledge that the Regulations improve safety, transparency, or quality standards. 36 feedback entries[286] (14.2%) discuss the withdrawal of niche or rare disease products, impacting patients with specific needs. Stakeholders raised similar concerns in the position papers, discussing delays in device availability, increased bureaucracy, and negative impacts on patient care, particularly for rare diseases and paediatric needs.

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[281] "I do not know/not applicable" respondents are included in the total.

[282] 45 from Company/Business, 30 from Health Providers, 15 from EU Citizens, 10 from Business Associations, 5 from Patient Organisations, 4 from NGOs, 3 from Academic/Research Institutions.

[283] 35 from Company/Business, 20 from Health Providers, 10 from EU Citizens, 8 from Business Associations, 3 from Academic/Research Institutions, 2 from NGOs.

[284] 40 from Company/Business, 20 from Health Providers, 10 from EU Citizens, 8 from Business Associations, 6 from Academic/Research Institutions, 3 from NGOs, 2 from Non-EU Citizens.

[285] 10 from Business Associations, 8 from Company/Business, 5 from Health Providers, 3 from Public Authorities, 2 from NGOs, 1 from Academic/Research Institutions.

[286] 15 from Company/Business, 10 from Health Providers, 5 from Patient Organisations, 3 from EU Citizens, 2 from NGOs, 1 from Public Authorities.

Regarding the functioning of the Union market, respondents to the PC did **not see the effectiveness of the Regulations in creating an even playing field for health institutions and in creating an even playing field for EOs** (MDR: 10% or 23/240 for health institutions and 10% agreement or 24/240 for EOs; IVDR: 9% or 10/113 for health institutions and 6% or 7/113 for EOs)[287]. As these figures show, scepticism was slightly higher regarding the effectiveness of the IVDR in creating an even playing field, compared to the MDR. The low level of support for the effectiveness of the MDR/IVDR in creating an even playing field was present across stakeholder types[288]. Feedback to the CfE discussed the contributions of inconsistencies in the interpretation, implementation, and costs of MDR/IVDR Regulations across Member States and NBs in creating an uneven playing field (112 out of 176 entries[289], 63.7%) The position papers discuss, across stakeholder types, the challenges and inconsistencies in implementing the MDR and IVDR. This undermines the goal of creating a level playing field for economic operators, identifying the size of a company, type of product, risk class, location/Member States, choice of NB, and inconsistent interpretations as factors which influence the playing field. In line with this, respondents to the PC were doubtful of the Regulations' effectiveness in ensuring the rules were applied fairly and impartially both before and after a device is CE-marked (24% and 29% respectively for MDR; 19% and 21% respectively for IVDR). Both the CfE and position papers (across all stakeholder groups) discussed the disproportionate impact on SMEs and start-ups because of relatively high compliance costs and administrative burdens compared to larger companies (67 out of 176 entries[290], 38.1% in the CFE).

There is **broad consensus that the MDR and IVDR regulatory frameworks do not adequately support innovation**. In the PC survey, just 1% or 3/240 agreed that the MDR, and 2% or 2/113 that the IVDR, supported innovation. 243 feedback responses[291] to the CfE (out of 360, 67.5%) reported the MDR/IVDR hinders innovation due to the regulatory burdens they impose. Challenges[292] cited include excessive documentation and unclear requirements, which stakeholders find divert resources from R&D to regulatory compliance. 78 entries[293] (out of 360, 21.7%) discuss lengthy certification timelines and their impact on innovation. Stakeholders find the Regulations discourage incremental and breakthrough innovations, delays market entry, and drives companies to prioritise non-EU

[287] "I do not know/not applicable" respondents are included in the total.

[288] Based on an analysis of the stakeholder types for which a sufficient number of responses was available to make a reliable judgement.

[289] 48 from Company/Business, 22 from Business Association, 15 from Health Provider, 10 from EU Citizen, 6 from Other, 5 from Academic/Research Institution, 3 from NGO, 2 from Public Authority, 1 from Trade Union.

[290] 38 from Company/Business, 12 from Business Association, 7 from EU Citizen, 5 from Health Provider, 3 from Academic/Research Institution, 2 from Non-EU Citizen.

[291] 89 from Company/business; 47 from Health provider; 36 from EU Citizens; 28 from Business Association; 15 from Academic/Research Institution; 10 from Other; 7 from Non-EU Citizens; 6 from NGO; 3 from Public authority; 2 from Trade Union; 1 from Patient organisation.

[292] CfE entries from EU citizens, health providers, company/businesses.

[293] 34 from Company/business; 16 from Health provider; 12 from Business Association; 8 from EU Citizen; 5 from Academic/Research Institution; 3 from Other.

markets like the U.S. and Asia (64 out of 360 entries[294], 17.8%). 112 entries[295] (31.1%) discussed the disproportional impact of the Regulations on SMEs and start-ups.

In line with this, the position papers analysis also revealed that stakeholders (across all stakeholder groups) are critical of the MDR and IVDR frameworks for stifling innovation, particularly for SMEs, startups, and low-risk devices. Common concerns include high costs, administrative burdens, lengthy approval processes, and regulatory unpredictability, which stakeholders feel divert resources away from R&D, delay market access, and encourage a shift of innovation activities to more predictable markets like the United States.

The position papers and CfE analyses revealed consensus that the MDR and IVDR, and their financial and regulatory burdens, **disproportionately affect SMEs**. 85.5% of CfE feedback responses which discussed impacts of the Regulations on SMEs (278 out of 325 entries[296]) discussed the disproportionate financial and administrative burdens of the MDR and IVDR on SMEs. Recurring themes in both the position papers and CfE include high certification costs, resource constraints, lengthy approval timelines, and complex documentation requirements, which hinder innovation, can lead to product withdrawals, and drive some SMEs out of the market. In the position papers analysis, one manufacturer association report states that 77% of companies responding to their survey reported negative effects of the MDR on their innovation activities.'[297] Another such association reports that '47.6% of large manufacturers and 54.4% of SMEs reported decreases in new medical device development'.[298] A peer-reviewed article reports 'about one-third of those surveyed indicated that they are having difficulty bringing innovative products to the market because of the MDR.'[299]

At the time of this study's implementation of the MDR/IVDR—when EUDAMED and the traceability requirements under the Regulations are not yet fully in place—**only a small proportion of stakeholders in the PC considered the Regulations to be effective in enhancing the transparency of devices and the traceability of devices within the EU** (MDR: 28% or 66/240 agreement for transparency and 39% or 93/240 agreement for traceability; IVDR: 19% or 22/113 agreement for transparency and 23% or 26/113 agreement for traceability). The most commonly referenced transparency issue in the CfE feedback responses (34 out of 121 entries referencing transparency[300], 27.9%) called for improved transparency in EUDAMED. The position papers support (across all stakeholder types) the MDR's and IVDR's goals to enhance transparency through EUDAMED, UDI,

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[294] 28 from Company/business; 12 from EU Citizen; 10 from Health provider; 8 from Business Association; 4 from Non-EU Citizen; 2 from Other.

[295] 52 from Company/business; 18 from Health provider; 14 from Business Association; 10 from EU Citizen; 8 from Academic/Research Institution; 6 from Other; 4 from Non-EU Citizen.

[296] 120: Company/Business; 45 EU Citizen; 35 Business Association; 30 Health Provider; 15 Other; 10 Non-EU Citizen: 8 Academic/Research Institution; 5 NGO; 4 Public Authority; 3 Trade Union; 2 Patient Organisation; 1 Consumer Organisation.

[297] Position paper of manufacturer.

[298] Position paper of manufacturer association.

[299] Position paper of academic.

[300] 10 Business, 8 Health Providers, 6 Business Associations, 4 EU Citizens, 3 NGOs, 2 Academics, 1 Public Authority

and public access to clinical data, and equally find EUDAMED's full implementation is critical for improving traceability and accessibility of safety and performance data.

42 CfE respondents[301] (out of 87 entries, 48.2%) expressed a **lack of trust in the regulatory framework** —both in its outcomes and in the framework itself. The position papers emphasise the importance of trust in the regulatory framework for medical devices, focusing on transparency, rigorous evidence, harmonised implementation, and robust oversight. One paper notes that the inefficiencies and unpredictability of the MDR and IVDR have eroded trust in the system among stakeholders, including patients and manufacturers: 'This affects confidence and trust in the system, its stakeholders and the reliability of medical devices approved under the system.'[302]

As the results above show, stakeholders view the MDR and IVDR as having failed to meet their objectives, notably in terms of supporting innovation and creating an even playing field for health institutions and EOs. In addition, there is evidence to suggest that the Regulations may have had unintended effects. Both the CfE and position papers analyses highlight the negative impact of the MDR and IVDR on the **availability of medical devices**. 393 feedback responses[303] to the Call for Evidence highlight concerns about reduced availability of medical devices due to stringent MDR and IVDR regulations. Indeed, a survey by a health professional association found that 49% of clinician respondents in Europe confirmed issues with medical device availability (number unknown), with particular impact on certain subspecialities such as paediatric cardiology.[304] 61% of European hospital pharmacists survey respondents (N=1251) indicated that medical devices shortages are a problem in their hospital.[305] Of the 393 feedback responses to the CfE, 70% (278 feedback responses[306]) referenced **market withdrawal of devices** due to high compliance costs, lengthy certification processes, and limited NB capacity. Stakeholders cited different figures related to withdrawals in both the CfE feedback and position papers: data from various sources provided by stakeholders suggested that between 46% (n unknown) and 54% (N=68) of manufacturers are planning to stop (or had stopped) producing or marketing some medical devices in Europe.[307] According to a manufacturers association, 58% of manufacturers that discontinue their products in the EU will continue to sell these products outside of the EU (N=393).[308] Various figures are provided on the potential decreases in availability of medical devices

[301] 15 from Company/Business, 9 from EU Citizens, 7 from Health Providers, 6 from Business Associations, 3 from Non- EU Citizens, 2 from NGOs.
[302] Position paper of manufacturer association.
[303] 139 company/businesses, 76 health providers, 62 EU citizens, 40 business associations, 22 other, 18 academic/research institutions, 9 NGOs, 8 non-EU citizens, 7 public authorities, 5 patient organisations, 3 consumer organisations, 2 trade union, and 2 notified bodies.
[304] CfE of health provider.
[305] Position paper of pharmacists.
[306] This figure contains feedback from the following groups: 96 from Company/Business; 58 from Health Providers; 42 from EU Citizens; 34 from Business Associations; 18 from Other; 10 from Academic/Research Institutions; 8 from NGOs; 6 from Public Authorities; 4 from Patient Organisations; 2 from Consumer Organisations.
[307] Study conducted by Gesundheid Österreich. Mentioned in CfE of health provider; 3 position papers of academics; position paper of manufacturer association.
[308] Position paper of manufacturer.

(withdrawal of between 20 - 53% of current products)[309] and IVDs (withdrawal of between 17 - 22% (of current products)[310], often presented in direct connection to the MDR and IVDR's bureaucratic burden.

3.2. Efficiency

The CfE and position papers analyses revealed **significant administrative burdens under the MDR and IVDR, emphasising inefficiencies, delays, and resource-intensive processes**.

In the CfE, 183[311] of 221 respondents (82.8%) explicitly criticise the excessive administrative burdens and documentation requirements under MDR and IVDR. Excessive documentation, redundant processes, and unclear guidance were generally highlighted. Respondents emphasised the need for digitalisation, harmonisation, and streamlined processes to reduce costs and resource strain: 46 entries[312] (20.8%) advocate for digitalisation and streamlined processes to reduce administrative burdens. All stakeholders agree on the importance of EUDAMED and it is seen as a critical tool for improving transparency and efficiency, but its incomplete rollout exacerbates challenges: 97 respondents[313] (43.9%) highlight delays, inefficiencies, or incomplete functionality of the EUDAMED database.

The position papers analysis mirrors these views. Significant administrative burdens are cited, such as extensive documentation, which strain resources. For example, a manufacturer association survey reports that 52% of the respondents (to the 2023-2024 survey) declared that the average certification time is in the range 13-18 months. A further 22% of respondents declared that this time is in the range 19-24 months.[314] Concerned stakeholders advocate for digitalisation, streamlined processes, and centralised systems to reduce redundancies and improve efficiency. A recurring focus on the delayed implementation and inefficiencies of the EUDAMED database also features in the position papers analysis. Differences emerge in focus areas: manufacturers emphasise the disproportionate impact on SMEs and innovation, while healthcare professionals and insurers prioritise transparency and data accessibility. Patients and public authorities stress

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[309] Position paper of manufacturer; position paper of healthcare professional.

[310] Position paper of healthcare professional Study performed by MedTech Europe (see https://www.medtecheurope.org/wp-content/uploads/2021/09/medtech-europe-survey-report-detailed-results.pdf) mentioned in: CfE of health provider and CfE of company/business.

[311] 63 from Company/Business, 33 from Health Providers, 28 from Business Associations, 22 from EU Citizens, 12 from Other, 8 from Academic/Research Institutions, 6 from Non-EU Citizens, 5 from NGOs, 4 from Public Authorities, 2 from Trade Unions, 2 from Consumer Organisations, 0 from Patient Organisations.

[312] 21 from Company/Business, 10 from Business Associations, 6 from Health Providers, 4 from EU Citizens, 3 from Other, 1 from NGOs, 1 from Academic/Research Institutions, 0 from Non-EU Citizens, 0 from Public Authorities, 0 from Trade Unions, 0 from Consumer Organisations, 0 from Patient Organisations.

[313] 38 from Company/Business, 18 from Health Providers, 15 from Business Associations, 10 from EU Citizens, 6 from Other, 4 from Academic/Research Institutions, 3 from NGOs, 2 from Non-EU Citizens, 1 from Public Authorities, 0 from Trade Unions, 0 from Consumer Organisations.

[314] Position paper of manufacturer association.

the importance of EUDAMED for safety and traceability but note current limitations such as information gaps or limited staff capacity that prevent full functionality.

In the public consultation, perceptions of the acceptability of the **administrative costs and compliance costs** associated with the MDR and IVDR were quite negative. For Phase 1[315] and Phase 2[316] activities, no more than 10% of respondents agreed that the administrative and compliance costs were acceptable. For Phase 3[317] and Phase 4[318] activities, perceived acceptability of costs was slightly higher for the MDR but not for the IVDR.

Level of agreement that…	Phase 1	Phase 2	Phase 3	Phase 4
…the administrative/ compliance costs associated with the **MDR** are acceptable	Administrative: 11/240 or 5% Compliance: 15/240 or 6%	Administrative: 9/240 or 4% Compliance: 10/240 or 4%	Administrative :28/240 or 12% Compliance: 31/240 or 13%	Administrative:25/ 240 or 10% Compliance: 36/240 or 15%
…the administrative/ compliance costs associated with the **IVDR** are acceptable	Administrative: 10/113 or 9% Compliance: 11/113 or 10%	Administrative: 7/113 or 6% Compliance: 7/113 or 6%	Administrative: 10/113 or 9% Compliance: 12/113 or 11%	Administrative: 5/113 or 4% Compliance: 9/113 or 8%

Perceptions about the likelihood of costs decreasing were pessimistic: less than 10% of respondents believed the costs resulting from the MDR would decrease once the Regulation was fully implemented, apart from Phase 4, about which respondents were slightly more optimistic (10-15%)[319]. For the IVDR, respondents were slightly more optimistic about the costs for Phases 1 and 4 decreasing once the Regulation was fully implemented (10-15%) but were pessimistic about the costs for Phases 2 and 3 (less than

[315] The survey question described the activities to be considered for phase 1 as follows: activities related to generating evidence on the safety and performance of devices; activities related to clinical investigations; activities related to setting up quality management systems; activities for the designation of notified bodies under the Regulation.

[316] The survey question described the activities to be considered for phase 2 as follows: activities concerning the initial certification of devices and the maintenance of certificates; activities concerning the first placing on the market or putting into service devices for which the conformity assessment does not involve a notified body; activities related to derogations to the conformity assessment.

[317] The survey question described the activities to be considered for phase 3 as follows: Activities for the compliance with post market obligations; activities related to vigilance; activities related to market surveillance.

[318] The survey question described the activities to be considered for phase 3 as follows: Activities for providing information on devices or certificates; activities providing guidance to the sector.

[319] Agreement that administrative cost will decrease MDR Phase 1: 19/240, Phase 2: 14/240, Phase 3: 19/240, Phase 4: 33/240. Agreement that administrative cost will decrease MDR Phase 1: 20/240, Phase 2: 19/240, Phase 3: 17/240, Phase 4: 35/240.

10%).[320] While optimism about costs decreasing was low across all stakeholder groups[321], there were some differences in patterns across phases. For both the MDR and IVDR, Notified Bodies were more optimistic about the costs decreasing for Phase 4 than for all other phases, health providers were most optimistic about costs decreasing for Phase 1 and public authorities were *least* optimistic about costs decreasing for Phase 3.

There was a perceived mismatch between the level of regulatory burden and the actual risks involved in certain contexts. In the CfE analysis, 65 entries[322] (19.7%) found the frameworks lack proportionality for specific contexts, highlighting the need for risk-based, context-specific approaches. As one company explained: "*even for low-risk, well-established products, the volume and complexity of required documentation is overwhelming*".

In the CfE analysis, 278[323] of 325 feedback responses (85.5%) discussed the disproportionate financial and administrative burdens of the MDR and IVDR on SMEs in particular. Recurring themes include high certification costs, resource constraints, lengthy approval timelines, and complex documentation requirements, which hinder innovation, can lead to product withdrawals, and drive some SMEs out of the market. Similarly, in the position papers analysis, the impact on SMEs was highlighted, with stakeholders sharing concerns about increased certification costs, limited access to NBs in the first years of MDR and IVDR implementation, and reduced innovation, leading to SMEs withdrawing products or deprioritising the Union market. Manufacturers, insurers, and healthcare professionals highlight the financial strain and market exits, while academics and NGOs emphasize the stifling of innovation and competitiveness.

The analysis of the EO survey pointed to **differences in costs based on manufacturer size (SME versus large)**. Taking the example of QMS certificates for annex IX (there were insufficient datapoints to analyse the results for annex XI by size), the average issuance costs charged to the EO during the period 01/01/2022 - 31/10/2024 were 641,878 EUR (N = 25) for first certificates and 882,988 EUR (N = 56) for last certificates. Figure shows how the costs vary by manufacturer size with large manufacturers (N = 33) paying significantly more than SME (N = 23) for the last QMS certificate (percentage difference of 165.06%). Costs for hiring an external consultant follow the same pattern, for last certificate issuance the percentage difference between SMEs and large manufacturers is

[320] Agreement that administrative costs will decrease IVDR Phase 1: 15/113, Phase 2: 10/113, Phase 3: 8/113, Phase 4: 18/113. Agreement that complying cost will decrease IVDR Phase 1: 17/113, Phase 2: 11/113, Phase 3: 9/113, Phase 4: 20/113.

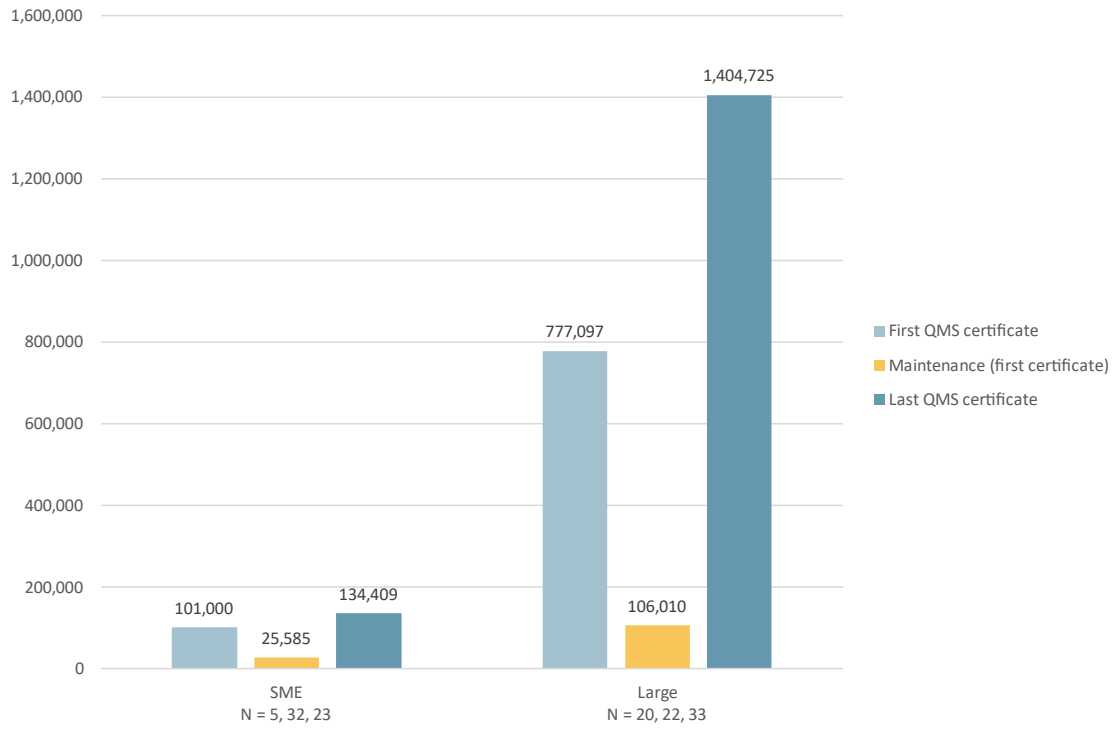
[321] Based on an analysis of the stakeholder types for which a sufficient number of responses was available to make a reliable judgement.

[322] 30 from Company/Business, 15 from Health Providers, 10 from Business Associations, 5 from EU Citizens, 3 from Academic/Research Institutions, 2 from Other. Note that these comments were originally classified as being related to relevance, but were judged to be more relevant to efficiency. The percentage (19.7%) is based on the total number of entries to the CfE.

[323] 120: Company/Business; 45 EU Citizen; 35 Business Association; 30 Health Provider; 15 Other; 10 Non-EU Citizen: 8 Academic/Research Institution; 5 NGO; 4 Public Authority; 3 Trade Union; 2 Patient Organisation; 1 Consumer Organisation.

185.20%. However, due to low response rate, this cost variation due to manufacturer size should be interpreted with caution.

Figure 4 Average costs (€) for QMS Annex IX certificates under MDR, by manufacturer size



3.3. Relevance

Respondents to the PC were sceptical about the relevance of the MDR/IVDR to emerging health challenges and evolving patient needs (51/240 or 21% agreement for the MDR; 18/113 or 16% agreement for the IVDR). Although respondents were slightly more positive about the relevance of the MDR/IVDR to cybersecurity[324], they were sceptical that the Regulations were relevant to emerging future technological and scientific innovation in the sector (4% and 8% agreement, respectively). In line with this, 48 CfE feedback responses[325] (13.6%) discuss misalignment of the Regulations with emerging technologies and needs. Concerns include inadequate support for emerging technologies such as AI, digital health, personalised medicine, genomics, 3D printing and software as medical device (SaMD). This feedback contrasts with the Regulations' objectives related to ensuring the availability of safe and performant devices, the smooth functioning of the internal market, and support to innovation and competitiveness, which stakeholders

[324] Public consultation: 71/240 respondents or 30% and 40/113 respondents or 35% agreeing that cybersecurity was addressed in the MDR and IVDR, respectively.

[325] 25 from Company/Business, 10 from Health Providers, 5 from Academic/Research Institutions, 4 from NGOs, 3 from Other, 1 from EU Citizens.

acknowledge remain relevant but insufficiently realised in practice. Stakeholders also highlighted that the lack of proportionate pathways – particularly affecting the SMEs, start-up, and niche or orphan devices – risks undermining access to critical technologies and weakens the sector's capacity to respond to evolving patient needs and health challenges. To overcome the lack of clarity in the regulatory framework, the feedback highlighted the need for clear and precise guidelines, for emerging technologies. The position papers analysis was aligned with this.

3.5. Coherence

35% (84/240) of respondents to the PC agreed that the provisions in the MDR are **internally coherent**, and 33% (78/240) agreed that the provisions of the MDR are coherent with the provisions of the IVDR. The same proportion (35%, 39/113) of respondents to the PC agreed that the provisions in the IVDR are internally coherent, and 44% (50/113) agreed that the provisions of the IVDR are coherent with the provisions of the MDR. Only one position paper cited an example of incompatible provisions: '[Provisions in Annex X, Art. 10 c, Article 20, and Annex X] were mutually incompatible and contradictory; their net result has been that in Europe no details of the regulatory review of clinical evidence relating to medical devices have been disclosed.'[326] In the CfE, no internal coherence issues were explicitly identified.

Perceptions of the **external coherence** of the MDR varied according to the Regulation with which it was being compared. Respondents to the PC were most likely to agree that the MDR was coherent with other EU rules in the field of market surveillance (33% or 78/240) and packaging and labelling (34% or 81/240), and least likely to agree it was coherent with other regulations in the field of eco-design (4% or 10/240). Respondents to the PC were most likely to agree that the IVDR was coherent with other EU rules in the field of cybersecurity (34% or 39/113) and market surveillance (31% or 35/113), and least likely to agree it was coherent with other regulations in the field of eco-design (4% or 4/113).

109 feedback responses to the Call for Evidence discussed the external coherence and alignment in the MDR and IVDR regulatory frameworks. 58 of these feedback responses [327] (53.2%) explicitly highlight misalignment or overlaps with other EU regulations (e.g., Artificial Intelligence Act[328] (AI Act), General Data Protection Regulation[329], the Clinical Trials Regulation[330] (CTR) and environmental legislation). The position papers call for better alignment between the MDR and IVDR and other frameworks, such as the AI Act[331],

[326] Position paper of academic.
[327] 20 from Business Associations, 18 from Companies, 10 from Health Providers, 5 from Academic/Research. Institutions, 3 from NGOs, 2 from Public Authorities.
[328] Regulation (EU) 2024/1689, OJ L, 2024/1689, 12.7.2024, ELI: http://data.europa.eu/eli/reg/2024/1689/oj.
[329] Regulation (EU) 2016/679, *OJ L 119, 4.5.2016, pp. 1–88*, ELI: http://data.europa.eu/eli/reg/2016/679/oj.
[330] Regulation (EU) No 536/2014, OJ L 158, 27.5.2014, pp. 1–76, ELI: http://data.europa.eu/eli/reg/2014/536/oj.
[331] 2 position papers of manufacturer associations.

GDPR[332], and pharmaceutical legislation[333,334,335], to reduce overlaps, contradictions, and administrative burdens. One position paper from a business association indicated that 58% of companies are concerned about the high level of complexity between the MDR and other regulations.[336] 34 CfE feedback responses[337] (31.2%) emphasise the need to integrate horizontal frameworks (e.g., AI Act, sustainability, cybersecurity) to avoid contradictory requirements.

Based on European Commission services experience, future reflections on coherence and interplay between MDR/IVDR and the following frameworks can be considered:

- The **Ecodesign for Sustainable Products Regulation (ESPR)**[338] aims to enhance the sustainability of certain products on the EU market. Unlike food and medicinal products, medical devices and IVDs are not exempt. When setting the potential ESPR requirements (such as on durability, reusability, environmental impact etc.), the need to not negatively affect the health and safety of patients and users should be taken into account. The phased introduction of ESPR requirements could eventually apply to medical devices, though the timeline remains uncertain.

- The **Basic Safety Standards Directive (BSSD)**[339] aims to ensure, among others, that patients are protected against the dangers arising from exposure to ionising radiation, including by setting requirements for the use of medical devices emitting ionising radiation (in radiology, radiotherapy, nuclear medicine). With respect to the interplay with MDR, activities such as acceptance and performance testing of devices, or vigilance and surveillance, call for cooperation between radiation protection and medical devices authorities. The interplay between BSSD and MDR is currently being investigated in the "SAMIRA MD study" under the SAMIRA Action Plan[340].

3.6. EU added value

Respondents to the public consultation agreed that it was **preferable to have a single EU regulation** in this field instead of individual national regulations (93% or 224/240 of respondents for MDR, 87% or 98/113 of respondents for IVDR). In line with this, in the position papers, stakeholders broadly agree that a unified regulatory framework enhances patient safety, supports innovation, and strengthens the EU's global competitiveness. The

[332] Position paper of manufacturer (large).
[333] Position paper of European body.
[334] Position paper of manufacturer (large).
[335] Position paper of manufacturer (SME).
[336] Position paper of manufacturer.
[337] 12 from Business Associations, 10 from Companies, 6 from Health Providers, 3 from Public Authorities, 2 from Notified Bodies, 1 from Trade Union.
[338] Regulation (EU) 2024/1781 OJ L, 2024/1781, 28.6.2024, ELI: http://data.europa.eu/eli/reg/2024/1781/oj.
[339] Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.
[340] European Commission website, *Radiological and nuclear technology in health*, SAMIRA Action Plan.

CE mark and centralised governance are seen as valuable tools for market access and efficiency.

However, although there was support for the idea of a single EU Regulation in principle, there were mixed views about the added value of the MDR and IVDR in terms of its effectiveness. Overall, 98 feedback responses to the CfE highlight concerns about the EU added value of the regulations. From the analysis of these feedback responses, the term "EU added value" was understood by stakeholders both in the sense of the EU as a market and in terms of EU regulations to regulate medical devices. Recurring themes include critiques of the regulations for stifling innovation, increasing costs, and driving companies to non-EU markets, which undermines the EU's competitiveness and added value.

Recurring themes around EU added value in the position papers analysis include the EU's leadership in harmonising the laws governing medical devices on the Union market under MDR and IVDR, fostering innovation, and ensuring safety and access to medical technologies. However, frequent critiques highlight the MDR's and IVDR's stringent requirements, which are seen as burdensome, hindering innovation, delaying market access, and driving companies to non-EU markets. Commonalities among stakeholders include recognition of the EU's role to create harmonised laws under one regulation, ensuring safety, and fostering innovation.

On the other hand, a large proportion of PC respondents agreed that the MDR and IVDR **decreased compliance and administrative costs** compared to having to comply with a different set of rules at the national level (MDR: 49% or 117/240 agreement with decreased compliance costs and 50% or 119/240 agreement for decreased administrative costs; IVDR: 58% or 65/113 agreement for decreased compliance costs and 56% or 63/113 agreement for decreased administrative costs). On the other hand, around half of the PC respondents believed that it was feasible to maintain adequately safe devices while reducing costs (45% or 109/240 agreement for the MDR; 42% or 48/113 agreement for the IVDR).

ANNEX VI. EFFECTIVENESS TABLES: EVIDENCE AND SCORING

To synthesise findings across diverse sources, the evaluation applies a five-point ordinal scale consistent with Tool #47 on proportionality:

- ++ Strong positive impact
- + Some positive impact
- 0 Neutral/mixed impact
- - Some negative impact
- -- Strong negative impact

Scores are assigned per evaluation question and then synthesised at section and criterion level. The scoring is qualitative but evidence-based: it is not mechanically derived from percentages but reflects a reasoned judgement through triangulation.

Applying a scoring system across all impacts ensures that findings from very different types of evidence can be compared in a transparent and proportionate manner. The MDR and IVDR generate a wide variety of effects: some are quantifiable (e.g. certification fees), while others are qualitative (e.g. perceived legal certainty, trust). Without a common framework, it would be difficult to synthesise these diverse results into an overall assessment of efficiency.

The five-point ordinal scale provides such a framework. It allows evaluators to translate heterogeneous evidence into a comparable format, highlighting whether impacts are positive or negative and to what extent. This ensures that the evaluation captures not only the magnitude but also the direction of change. Importantly, the scores are not a mechanical output of survey percentages; they reflect a reasoned judgement through triangulation of multiple sources, consistent with the Better Regulation Toolbox.

This approach offers several advantages:

- **Transparency**: stakeholders can clearly see how different impacts have been weighed and judged.
- **Comparability**: results across stakeholder groups and regulatory areas can be aligned on a single scale, allowing for cross-cutting synthesis.

- **Proportionality**: the scoring highlights which impacts are most significant, ensuring that minor issues do not overshadow major burdens or benefits.

At the end of the analysis, results are synthesised in an overview table, which shows:

- Each evaluation criterion
- Sub-sections/questions under it
- The assigned scores (--/–/0/+/++)
- Key supporting evidence

Legend:

- CAPA: Corrective and Preventative Action
- CECP/PECP: Clinical/Performance Evaluation Consultation Procedure
- CEF: Compliance Exchange Form
- CEN: European Committee for Standardization
- CENELEC: European Committee for Electrotechnical Standardization
- CER/PER: Clinical/Performance Evaluation Report
- CfE: Call for Evidence
- CI: Clinical Investigation
- DA: Designating Authority
- e-IFU: Electronic Instruction of Use
- EC: European Commission
- EMA: European Medicine Agency
- EO: Economic Operators

- EO survey: Economic operator survey' conducted in the context of the Targeted Evaluation of the MDR and IVDR
- EPO: European Patents Office
- Eudamed: European database on medical devices
- FSCA: Field Safety Corrective Action
- FTE: Full-Time Equivalent
- Governance study: by Ernst and Young
- HCP: HealthCare Professional
- IEC: International Electrotechnical Commission
- IMDRF: International Medical Device Regulators Forum
- ISO: International Organization for Standardization
- IVD: In Vitro Diagnostic Medical Devices
- IVDR: In Vitro Diagnostic Medical Devices Regulation
- JACOP: Joint Actions on Compliance of Products in the EU and EFTA countries
- JAMS: Joint Actions on Market Surveillance
- JAT: Joint Assessment Team
- MD: Medical Devices
- MDR: Medical Devices Regulation
- MDCG: Medical Device Coordination Group
- MDSAP: Medical Device Single Audit Program
- MEDDEVs: guidance documents written by competent authorities under the Medical Devices Directives (MDD, AIMDD, IVDD)
- MIR: Manufacturer's Incident Report
- MS: Market Surveillance
- MTE: MedTech Europe
- NB: Notified Body
- NB survey: Notified body survey conducted in the context of the Targeted Evaluation of the MDR and IVDR
- NBCG-Med: Notified Body Coordination Group

- NBO: Notified Body Oversight working group within the MDCG
- NBOG: Notified Body Operations Group (NBOG).
- NC: Non-Conformity
- NCA: National Competent Authority
- NCA survey: Targeted national competent authority survey, conducted in the context of the Targeted Evaluation of the MDR/IVDR.
- OJEU: Official Journal of the European Union
- PC: Public Consultation
- PMS: Post-Market Surveillance
- PP: Position Papers
- PS: Performance Study
- PSR: Periodic Safety Report
- QMS: Quality Management System
- RC workshop: reality check workshop (with manufacturers or with healthcare professionals, users, patients)
- Vig: Vigilance
- WET: Well-Established Technology
- WG: Working Group

Table 1: Scoring of legal certainty, transparency and trust

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
To what extent has the MDR/IVDR **increased legal certainty** for stakeholders (definitions, procedures, consistency of application)?	• number of classification/qualification disputes (Article 52(3) and (4) MDR/47(3) and (4) IVDR) • volume of clarification requests to NCAs	• Most countries report no increase in disputes; One Member State reported a decrease from 77 (MDD/AIMDD) to 2 (MDR/IVDR) (NCA survey) • 1263 disputes on which a court decision has been taken in relation to medical devices under MDD/AIMDD between 2014 and 2021 (data from the NCA survey, 13 respondents) • 34 disputes on which a court decision has been taken in relation to IVDs under IVDD between	• 86% of respondents state that unclear definitions, inconsistent interpretations, and vague guidance documents create legal uncertainty, while 61% of them highlight variability in interpretations by notified body and national authorities as causes that lead to inefficiency and unpredictability (CfE) • Widespread critique of ambiguous definitions,	0 (neutral/mixed)	• Despite missing data from several Member States, fewer national legal disputes in which a court decision was taken reported under the Regulations so far compared to the Directives. • Although quantitative trend suggests fewer disputes overall, qualitative evidence points to persistent uncertainty. • The Regulations introduced various EU

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
		2014 and 2021 (data from the NCA survey, 5 respondents) • 787 disputes on which a court decision has been taken in relation to medical devices under MDR between 2021 and 2024 (data from the NCA survey, 13 respondents) • 11 disputes on which a court decision has been taken in relation to IVDs under IVD between 2021 and 2024 (data from the NCA survey, 5 respondents) • 167 reported decisions taken on the	inconsistent application across MS (PP) • 75% of respondents disagree or strongly disagree that a robust, transparent, predictable, and sustainable regulatory framework exists (MD), while 77% believe the same for IVD (PC) • approximately 40% of respondents believe that the guidance documents produced by MDCG enhance legal clarity on provisions of the Regulations (both MD and IVD), while 18%		level procedures with the aim of enhancing legal certainty, for example classification disputes (Art. 52(3) and (4) MDR/47(3) and (4) IVDR) and to determine the regulatory status of products (Article 4 MDR) i.e. qualification matters. • The impact of guidance on small economic operators is unknown and hard to estimate.

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
		classification of devices in cases of a dispute between the MF and the NB under the MDD/AIMDD between 2014 and 2021 (reported by 11 countries), while under MDR and IVDR the numbers dropped to 23 and 3, respectively (NCA survey)	(MD) and 21% (IVD) are neutral (PC) • One third of stakeholders in the CfE call for clearer, harmonised, and binding guidance documents to reduce legal uncertainty and improve predictability under the MDR and IVDR, suggesting a centralised EU-level support or mediation to resolve disputes		• Guidance volume is high, but clarity and consistency perceived as insufficient. • Helsinki procedure is not efficient: average number of countries that participate is 11 and timeframe to reach a decision is too long.
	• number of guidance documents issued (MDCG) • perceived clarity of guidance	• 50+ MEDDEV + NBOG documents (EC) • 600+ number of pages in the MEDDEV + NBOG documents (EC) • 100+ MDCG guidance docs issued since 2017		0/+ (mixed to some positive)	

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
		• 1500+ number of pages in the MDCG guidance documents (EC)			
	• use of EU-level procedures	• Helsinki procedures: 68 ongoing, 11 published, 2 abandoned, and 9 non-majority under MDR/IVDR (EC) • 75% of procedures are on qualification, while 25% on classification (EC) • The average duration of a Helsinki procedure is 347 days (EC)		- (some negative impact)	
To what extent have the Regulations **improved transparency** for	• number of CE-marked devices • number of reports published	• 600.000+ UDIs registered in EUDAMED in Q1 2025 (EUDAMED)	• 27.9% of respondents cited the need for improved transparency in EUDAMED (CfE)	- (some negative impact)	• Although the gradual rollout of EUDAMED is progressing, until its full operationality,

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
stakeholders (e.g. EUDAMED, SSCPs)?	• number of published DA Summary Reports	• 75.000+ users registered in EUDAMED in Q1 2025 (EUDAMED) • 1300+ certificates registered in EUDAMED in Q1 2025 (EUDAMED) • 2800+ clinical investigation reports and summaries reported, out of which 957 (33%) are published (EO survey) • 4400+ performance studies reports and summaries reported, out of which 21 (0.5%) are published (EO survey) • 3400+ summaries of clinical safety and	• There is an emphasize need for transparency in MDR, particularly through the implementation of the EUDAMED database, public access to safety and performance data, and measures like UDI. Recurring themes include the importance of transparency for trust, traceability, and informed decision-making, as well as critiques of delays in EUDAMED's implementation and the lack of transparency in Notified Body processes,		centralised device data on the Union market remains incomplete. This stems primarily from the gradual implementation process rather than the design of the regulatory framework. • Quantitative evidence is difficult to rely on and observations are mostly informed by qualitative evidence. • Limited SSCPs available to date. It is difficult to tell if low publication rates by

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
		performance (SSCPs) reported, out of which 927 (27%) are published (EO survey) • 1500+ summaries of safety and performance (SSPs) reported, out of which 197 (12.6%) are published (EO survey) • 18/20 countries that have MDR NBs designated have published their monitoring & on-site assessment activity reports in 2024 (MS annual reports) • 7/11 countries that have IVDR NBs designated have	clinical evidence, and certification costs (PP)		manufacturers is due to the absence of Eudamed module. • It is not possible to predict whether the full availability of EUDAMED will result in 100% transparency of all information that some stakeholders request. • Availability of information does not always translate to awareness on it. It is unclear whether awareness of available information will

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
		published their monitoring & on-site assessment activity reports (MS annual reports)			increase for healthcare professionals, patients and users.
	• perceptions of stakeholders on transparency	/	• 74.7% of respondents disagree or strongly disagree that "robust, transparent, predictable and sustainable regulatory framework exists" (PC) • 52% of respondents disagree or strongly disagree that the MDR and IVDR have contributed to achieving transparency of information on devices in the EU (PC)	- (negative impact)	

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
To what extent have the Regulations **increased trust of patients, professionals** and industry in the EU regulatory system?	• perceptions of stakeholders on trust	/	• 55% of respondents disagree or strongly disagree that the MDR has contributed to achieving trust in the regulatory system, while 54% believe the same for IVDR (PC) • For both MD and IVD, EOs are more negative on whether the Regulations have contributed to achieving trust in the system, while NB are more positive compared to other stakeholders on	-- (strong negative impact)	• There is no quantitative data available on the level of trust. • Qualitative data, albeit from limited sources, does reveal important barriers to trust. • There is no data on the level of trust in the system before the introduction of the Regulations, therefore the evolution is hard to assess. • No major safety crises with MD/IVD have occurred

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
			achievement of trust in the system (PC) • 48.2% of respondents shared the perspective of the erosion of trust in the regulatory framework, with 20% respondents mentioning trust in relation to transparency, safety, and accountability (CfE) • At the same time, academics, healthcare professionals, insurers, and manufacturers agree that transparency and rigorous safety standards enhance trust in medical		since the introduction of the Regulations.

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
			devices and regulatory frameworks. Similarly, PMS and patient engagement are seen as trust-building measures (PP)		

Table 2: Scoring of notified bodies, conformity assessment procedures and clinical evidence

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
To what extent are **notified bodies designated** and overseen effectively and consistently across the EU?	• Context of notified bodies • Level of harmonisation in designation of NBs • Level of harmonisation in monitoring of notified bodies by designating authorities • Level of coordination	• Gradual increase of NBs over time - Total of 51 MDR & 18 IVDR (EC). • 12 MDR & 6 IVDR applications for designation ongoing (EC). • 13 applications withdrawn (9 MDR & 4 IVDR) 4 from the UK and 1 from CH. • Designation of NBs takes an average of 1041 days (median: 1022 days) for MDR and 1166 days (median: 1296 days) for IVDR.	• Stakeholders outlined criticism of capacity shortages in terms of number of NBs designated [now a solved issue for MDs] and availability for review under specific codes, inconsistent interpretations of regulations, and delays in certification processes and lack of harmonisation (PP). • 112 entries (40.7%) featured capacity constraints of NBs (CfE). • Class B and C IVDs now require NB involvement. Increased demand for IVDR notified bodies compared to IVDD. • There has been no change in monitoring structures between the	- (negative)	• Strong bottleneck on NB capacity at the beginning. Resolved now for MDR. • Code coverage is not evenly spread. Whilst most codes applied are obtained, highly specialised codes have low coverage. • Scope extensions require following the whole designation process. • Most designation NCs are in process and resource requirements. Significant variation between Member States.

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
		Positive evolution. Latest body to apply and get designated took 745 days for MDR and 686 days for IVDR (EC). • Longest steps in designation process: on-site assessment to CAPA (245 days for MDR and 194 days for IVDR) and CAPA JAT opinion to national DA's final report (197 days for MDR and 134 days for IVDR)(EC). • 92% MDR and 97% IVDR of codes applied	Directives and the Regulations. Key monitoring activities are performed by national authorities independently without central oversight (the only information shared is via the national DA annual report). • Calls for harmonised practices, improved transparency, and streamlined oversight mechanisms of notified bodies. Frequently mentioned solutions include harmonised oversight, centralised governance, and improved coordination to ensure consistency and efficiency. Proposals for centralizing governance to oversee Notified Bodies are suggested (PP).		• The number of NBs in a country does not correlate with the number of national experts dedicated to JAT process. • NBs and DAs, and their activities, are not sufficiently coordinated nor harmonised. This impacts the smooth functioning of the internal market.

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
		for by NBs were obtained. • 3 out of 9 requests for scope extensions under the Regulations to date already completed. • 21 NBO and 12 NBCG-Med meetings; 29 MDCG-endorsed documents and 3 NBCG-Med documents (EC).	• 275 entries to the CfE discussed challenges with the NB system under the Regulations. Recurring themes included limited capacity, long delays, inconsistent interpretations of regulations, high costs, and lack of harmonisation across NBs (CfE). • 88 entries (32.0%) discussed the need for harmonisation and oversight with calls for centralised governance, standardised processes, and improved coordination (CfE).		
To what extent are **conformity assessments** carried out effectively,	• Quality of conformity assessments • Level of predictability of	• The number of NB FTEs has continuously increased. >1,500 of NB FTEs (>30%) are dedicated to	• NBs indicate that most of the applications they receive are of low quality and incomplete (NB survey).	-- (strong negative)	• Lack of information on certification demand. Unknown what would constitute 'sufficient' resources.

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
predictably and consistently?	conformity assessment	administrative and supporting tasks (NB survey). • Issuance of a new certificate takes 6-18 months (QMS only) and 13-24 months (QMS and product) (NB survey). • Half of the total time to achieve certification is spent with the manufacturer (EO and NB survey). • The estimated reduction in length of the conformity assessment was <25% or no reduction at all for the	• Most refusals of certification applications are due to *'outside scope of notified body's designation'* (631/1,149 or 54.9%), *'application not complete'* (179/1,149 or 15.6%), and *'wrong qualification of product/classification of device'* (148/1,149 or 12.9%) (NB survey). • Manufacturers disagree that conformity assessment activities of NBs are harmonised (PC). • Respondents are more likely to disagree that conformity assessment activities of notified bodies are harmonised for the Regulations compared to the Directives (PC).		• High dissatisfaction with predictability of NB processes (CfE, PP, workshop). • Inefficiencies, delays, and lengthy, inflexible and unpredictable processes are often cited as causes of delays and high costs (CfE). • Manufacturers and industry associations emphasised reducing administrative burdens and introducing fast-track pathways, while healthcare professionals and insurers stressed maintaining robust safety

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
		majority of experiences of structured dialogue (NB survey).	• <50% stakeholders agreed MDR contributed to a level playing field in assessments, and that conformity assessments were predictable in duration (PC). • Stakeholders criticised inefficiencies, delays, and lengthy, inflexible and unpredictable processes resulting in knock-on delays and high costs, particularly for SMEs, orphan devices, and low-risk products. Recurring themes raised included inefficiency, complexity, and unpredictability (PP). • Calls for streamlined processes, binding timelines, harmonised methodologies, and reduced duplication are prevalent (PP).		standards and streamlined assessments for orphan devices (PP).

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
To what extent have requirements for **clinical evidence** improved device safety and performance?	• Level/Quality of clinical data available for assessment • Level of access to external scientific and clinical expertise in regulatory process	• Average cost of clinical evaluation is EUR 105,654.37 (lowest for class Ir MDR: EUR 27,764; highest for class III MDR: EUR 246,609) (EO survey). • The number of CI applications has remained stable, with the proportion of granted (~85%) versus denied (~15%) also remaining stable (NCA survey). • The number of PS applications has increased (NCA survey).	• New structures for scientific advice have been established. • 71.2% NBs reported that over >½ of CERs/PERs are incomplete or inaccurate, with >50% indicating that >¾ of the CERs/PERs are incomplete or inaccurate (NB survey). • CI/PS reports and their summaries are not being made public (<10% for MDs and <0.5% for IVDs). • 51.1% (or 23/45) notified bodies indicated that less than half of manufacturers carry out the foreseen activities in compliance with their PMCF plan for class III and implantable medical devices (NB survey).	0/+ (mixed with some positive)	• R&D continues to occur. • Regulatory advice is cited as a potential aid to the system. • A central structure for coordination of multi-national clinical investigations is cited as a potential aid to the system (RC workshop). • There is significant variation in the number of applications to conduct clinical investigations that countries receive. • Whilst data gathering has increased, NBs report that evaluations are incomplete

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
		• The number of PMCFs remains low, but has steadily increased (NCA survey). • CIs for research purposes have increased (NCA survey). • 77 CECP/PECP submissions to expert panels in 2024 alone, and 31 opinions issued since their inception (EMA) • Expert panels 2025: 32 opinions on NB's clinical assessment of high-risk medical devices (CECP), 21 views on the performance evaluation of	• 43.8% (or 14/32) of HCPs agree or strongly agree that there is more clinical data available on medical devices today compared to in 2017, and 40.6% (or 13/32) that it is of better quality (PC). • Stakeholders perceive that clinical evidence, and its availability have increased (RC workshop). • Early dialogue is seen as key for planning and developing CIs that will bring useful clinical evidence (RC workshop). • 211 entries to the CfE referenced requirements for robust clinical evidence. The disproportionate requirements for clinical evidence were discussed by 78 entries		and HCPs/users that is not available. • Some data collected (e.g. perceptions re proportionality of requirements for low and medium risk devices) is

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
		class D IVDs (PECP) (EMA) • 53.2% (or 25/47) notified bodies indicated that more than 75% of CERs/CERs are incomplete or inaccurate. 72.3% (or 34/47) indicate that more than half are incomplete or inaccurate (NB survey).	(36.7%), particularly in relation to low-risk and legacy devices (CfE). • Challenges for SMEs and startups were highlighted by 52 entries (24.6%), with the excessive burden resulting in high costs, delays, and resource (CfE). • 49 feedback entries (23.2%) maintain that legacy devices with proven safety and performance should not require duplicative or new clinical evidence (CfE). • Patient organisations highlighted challenges in meeting clinical evidence requirements for rare diseases, while an NGO called for greater representation of unrepresented groups (e.g. women,		more appropriate for and has been used in *section 4.1.2 'Efficiency'* of the SWD or *section 4.2. 'Relevance'* (e.g. re proportionality of requirements for niche and orphan devices)

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
			children) in clinical investigations (PP). • Manufacturers advocated for streamlined processes and real-world evidence, whereas regulators and insurers stressed maintaining high standards (PP).		

Table 3: Scoring of market functioning and even playing field

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments/data gaps
To what extent have the Regulations affected **competitiveness and innovation** of EU industry?	• number of patents • scientific advice provided by expert panels • number of devices on Union market (as registered in EUDAMED to date)	• 21168 devices under IVDD registered in EUDAMED • 206179 devices registered under MDRR in EUDAMED • 34661 devices registered under IVDR in EUDAMED • 511086 devices registered under MDR in EUDAMED (EC, July 2025) • number of patent applications increased by 19% between 2017 and 2024 (EPO) • patents granted increased by 29.5% between 2017 and 2024 (EPO) • Expert panels 2024: the number of CECPs grew with		0/+ (mixed to some positive)	• In 2024, whilst the highest number of granted patents originated from the US, the EU was in the 2nd place, with nearly 40% fewer patents than the US (EPO). • The number of patents granted in Europe increased between 2009 and 2020, experienced a decline in 2021 coinciding with the implementation of the MDR, but recovered by 2024 (EPO). • Number of devices and new devices on market cannot accurately be

		approx. 720% between 2021 and 2024 (EMA report) • 6 published scientific advice by expert panels (on MDCG request) for medical device and IVDs (EMA website)			determined in the absence of fully functional and mandatory EUDAMED. Even with limited data in EUDAMED so far due to voluntary registrations, trend analysis is not possible.
	• international participation	• EU is active in 7 out of 8 active IMDRF WGs (IMDRF website) • 8 MS have in total 15 experts participating in these WGs (IMDRF website) • 1,434 MDR and 180 IVDR certificates have been issues on the basis of the MDSAP/MDR-IVDR combined audit (NB survey) • EU is aligned with 84% of the IMDRF guidance (IMDRF) • about 85% of the 326 harmonised standards	• participation in global governance efforts (e.g. IMDRF, MDSAP) is encouraged and supported to enhance market access and reduce trade barriers (Webinar on the targeted evaluation MDR/IVDR: International Partners May 2025, including , Switzerland, the UK, and Australia), there is need for improved communication and better alignment with international partners, as well as better	0/+ (mixed to some positive)	• Since 2017, there are fewer operational bi-lateral international agreements (e.g. mutual recognition agreements) than under Directives. However, this can be influenced by other factors (e.g. trade and political developments) than the regulatory framework. • EU's involvement in IMDRF WGs has increased in 2024/2025 after decreasing for a number of years due to focus on

		requested by the Commission from CEN and CENELEC to support MDR/IVDR are based on international standards from ISO and IEC (eNorm Platform) • 26 of the 38 MDR/IVDR harmonised standards published in the OJEU are based on ISO/IEC standards (eNorm Platform) and 12 are purely European standards.	communication on safety issues and broader EUDAMED access.		MDR/IVDR implementation. • Available EU harmonised standards are mostly based on with international standards. • Measures of how EU remains competitive on international stage are difficult to interpret with data available.
	• European MD market • European IVD market	• the European medtech market is estimated at €170 billion in 2024, making it the world's second largest with 26.4% of global share, compared to the US (46.4%), China (6.5%), and Japan (4.7%) (MTE report) • there are more than 38,000 medical technology companies in Europe, out of	• the main trade partners for medical devices in Europe are the US, China, Japan, and Mexico (MTE report) • the challenges in the innovation climate have intensified by 2025, significantly affecting SMEs and start-ups as reported by stakeholders (CfE, PP)	0/+ (mixed to some positive)	• Compared to 2017, the overall market is larger and more resilient, with long-term average annual growth (market expansion and rising demands however not in terms of number of devices, as this is not measurable). • Data on this topic remains limited, as findings rely

		which 90% are SMEs (MTE report) • there are more than 930,000 employees in the medical technology industry (MTE report) • the European MD market has been growing on average by 6.0% per year over the past 10 years (MTE report) • the annual growth rate for MD has varied between 2.4% (2017) and 9.3% (2015) (MTE report) • the European IVD market has been growing 4.3% on average, hitting the record 40% in 2021 (MTE report) • Europe has a positive medical devices trade balance of €5 billion in 2024 (MTE report)			primarily on a single source (MedTech Europe facts & figures 2025 i.e. MTE Report). • The growth in the market based on manufacturer prices does not indicate proportional increase in innovation or competitiveness, as the growth rates rather indicate market expansion or rising demands. • The EU has maintained a strong export position, but more companies report shifting innovation and market entry to other regions – particularly the US – due to regulatory predictability and speed (CfE, PP).

	• perceptions of stakeholders on innovation and competitiveness	• 31% of respondents in the governance study totally disagree and 29% somewhat disagree that the EU MDR/IVDR frameworks support the placing on the Union market of highly innovative devices • 60% of respondents in the governance study believe that MDR does not stimulate at all the introduction of highly innovative devices on the Union market, while 48% believe this for IVDR • 65% of stakeholders strongly disagree that the MDR contributed to innovation in the medical device sector in the EU (PC) • 41% of stakeholders disagree, while 33% strongly disagree that the MDR contributed to the competitiveness of the	• stakeholders from the governance study are sceptical regarding the adaptability of the MDR/IVDR to support technological innovation in the sector over the next 5-10 years • the key regulatory barriers for the industry to bring innovative devices to the Union market are considered to be the administrative burden and costs of regulatory approval, followed by the length of the certification and recertification process (CfE, PP)	-- (strong negative impact)	• Data collected through multiple sources reveals broad consensus across stakeholders that the EU's MDR/IVDR regulatory frameworks hinder innovation, particularly for SMEs, start-ups, and niche markets. Common concerns include high costs, administrative burdens, lengthy approval processes, and regulatory unpredictability, which divert resources from R&D and delay market access (CfE, PP, PC, governance study)

		medical device sector in the EU (PC)			
To what extent have the Regulations ensured a **level playing field for economic operators** across the EU?	• single-use devices • n. of certificates issued by notified bodies for relabelling/repackaging activities	• 17/30 countries prohibit the use of reprocessing of single use devices (study on the implementation of Article 17 MDR) • 10/30 allow the use of reprocessing of single use devices (study on the implementation of Article 17 MDR) • 3/30 did not take a decision (study on the implementation of Article 17 MDR) • 6/38 surveyed NBs certify single use devices or reprocessing single use devices (report on the operation of Article 17 MDR) • 24 certificates for quality management systems issued by notified bodies under Article 16(4) MDR and 13	/	0 (neutral)	• Despite efforts to reduce fragmentation on the single market, approach to the regulation of reprocessing of single-use devices under the MDR Article 17 in MS remain disparate and the safety & performance of these devices has not necessarily increased. Data is limited however and only based on one existing study.

		under IVDR, for re-labelling and re-packaging activities by importers and distributors under Regulations (GOG survey)			
	• perceptions of stakeholders of even playing field for economic operators	• 63.7% of stakeholders state that inconsistencies in the interpretation, implementation, and costs of MDR/IVDR Regulations across MS and NBs create an uneven playing field (CfE) • 38.1% highlight that the MDR/IVDR disproportionately affects SMEs compared to larger companies, creating competitive disadvantages (CfE)	• SMEs are consistently highlighted as disproportionately burdened by high compliance costs and limited NB access, creating an uneven playing field (CfE, PP) • Stakeholders share the need for harmonised regulations, consistent NB practices, and reduced disparities across MS to ensure fairness (CfE, PP) • Stakeholders also highlight fragmented implementation of MDR/IVDR, creating regulatory uncertainty and competitive disadvantages (CfE, PP)	- (some negative impact)	• Data collected through the CfE, PP, and PC comes with certain limitations as it is mostly qualitative. • The main causes of the uneven playing field for economic operators are regulatory inconsistencies across NB and MS, fragmented national implementation, and disproportionate burdens on SMEs.

To what extent has the MDR/IVDR affected the **availability of devices** on the Union market (shortages, withdrawals, delays)?	• number of devices on EU market • certificates • remaining transition of devices	• >2,000,000 medical technologies, categorised into >7,000 generic devices groups (WHO) • 10,554 MDR certificates by Annex until October 2024 (GOG survey) • 1,273 IVDR certificates by Annex until October 2024 (GOG survey) • 28% of NB indicated that less than 25% of their clients with certificates under the Directives have completed the transfer to MDR of all devices intended to be certificated (GOG survey) • 28% indicated that between 76 and 99% of their clients with certificates under the Directives have completed the transfer to MDR of all devices intended to be certificated (GOG survey)	/	0/- (mixed to some negative)	• Limitation is that quantitative data available is limited due to on-going implementation and tools e.g. EUDAMED not yet available to fully capture. • Scoring is therefore based also largely on qualitative data. • GOG monitoring survey has been going since April 2023 (1st NB survey) to April 2025 (14th NB survey). • Accurately determining the number of medical devices currently available on the Union market remains is not yet possible. lack of reliable baseline data makes it challenging to estimate what proportion of

		• 46% of NB indicated that less than 25% of their clients with certificates under the Directive have completed the transfer to IVDR of all devices intended to be certificated (GOG survey) • 15% of NB indicated that > 50% of their clients have completed the transfer (GOG survey)			devices may not transition to the Regulations. • Key reasons for discontinuing devices from the market include low revenue, low sales volume, replacing the products, and life cycle, based on the EO survey. Position paper emphasises certification delays, high compliance costs, and bureaucracy. • Both the number of applications and the number of certificates has constantly increased since the introduction of the Regulations. • Stakeholder perceptions on availability vary depending on the group, with manufacturers most
	• potential shortages • stakeholders' perceptions on shortages	• almost 60% of HCP/HCP associations reported that in the last 3 years they experienced problems purchasing/being supplied with relevant devices – MD (PC) • 43% HCP/HCP associations and 65% of the health institutions reported the same for IVD (PC) • 393 stakeholders highlight concerns about reduced	• 70% of surveyed stakeholders referenced market withdrawal of devices due to high compliance costs, lengthy certification processes, and limited NB capacity • 61% of European hospital pharmacists responded to a survey that medical devices shortages are a problem in their hospital	- (some negative impact)	

		availability of medical devices due to stringent MDR and IVDR regulations (CfE) Since early 2025, circa 40 Article 10a notifications for discontinuation/interruption have been received, a third of them affecting devices with no alternatives (EC, internal sources).	• General consensus amongst stakeholders that introduction of Regulations has caused problems with the availability of devices in the EU (CfE, PP) • Economic operators were the least likely to agree that the Regulations contribute to the availability of devices on the EU, whereas citizens and patient associations were the most likely to agree (PC)		likely to indicate problems with availability and citizens and patient associations least likely to indicate problems with availability. • A total of 138 MD and 73 IVD manufacturer organisations participated in the MTE 2024 survey, with an almost equal distribution between large companies and SMEs.
	• orphan devices	• over 52% of MD respondents that produce orphan devices indicate they will transfer all their orphan devices to the MDR and 29% report they do not plan to transfer any (MTE 2024 report) • 26.6% of IVD manufacturers reported they	• 47% of respondents somewhat or totally disagreed that the MDR supports the placing on the Union market of orphan devices versus 14% who somewhat or totally agreed (governance study) • The perceived limited adaptability of the		• Orphan devices are seen as critical to deliver essential therapy to patients with little alternatives. However, many manufacturers indicate their discontinuation of these devices.

		will transition less than 5% of their portfolio of orphan devices (MTE 2024 report)	regulatory framework to orphan devices was often linked to the difficulties with obtaining the required clinical evidence for these device (governance study) • NCAs considered that there are difficulties in predicting the availability of orphan devices for patients and end users (governance study)		
To what extent do the Regulations address **specific needs of patients and users** (e.g. rare diseases, paediatrics, accessibility)?	• number of health institutions • number of in-house devices • number of derogations	• 30,776 health institutions reported by 13 CA who responded to the NCA survey • 79 health institutions having notified IH MDs in 10 CAs (NCA survey) • 67 health institutions having notified IH IVDs in 10 CAs (NCA survey) • In a BioMed Alliance survey, the labs which participated indicated they	• 46% of respondents agree that the MDR contributed to protecting the health of patients in relation to medical devices, while 44% believe the same for IVD (PC) • 40% of respondents agree that MDR contributed to protecting the health of users in relation to medical	0/- (mixed to some negative)	• Although the Regulations are designed to address specific needs of patient and target groups, implementation challenges often prevent these needs from being effectively met, particularly in the case of in-house devices. • Limited to no data was collected for in-house devices, which limits the

		had 52% CE-IVDs, 14% modified/off-label CE-IVDs, 8% RUOs, and 26% IH-IVDs • 10 national derogations for “compassionate use” (MD) started before 2017 and 48 started after 2017 (EC) • 750 national derogations granted for Art 59(2) MDR and 49 for Art 54(2) IVDR (EC)	devices, while 35% believe the same for IVD (PC)		analysis and conclusions for this topic. • While data on compassionate use is not collected, the MDR captures national notified derogations, which increased during COVID and then stabilised, with significantly fewer notifications for IVDs compared to MDs. • EU-wide derogation mechanism has been used only once, with stakeholders pointing to burdensome procedures as a likely reason for its limited uptake. • Stakeholders call for clearer definitions and regulatory frameworks, emphasising the need for

					flexibility to accommodate innovation and the unique needs of in-house devices. • Healthcare professionals and institutions report that regulatory requirements are unclear and burdensome, significantly impacting the development of in-house devices.

Figure 1: Europe in the world of medical device market based on manufacturer prices *(MTE facts and figures 2025)*

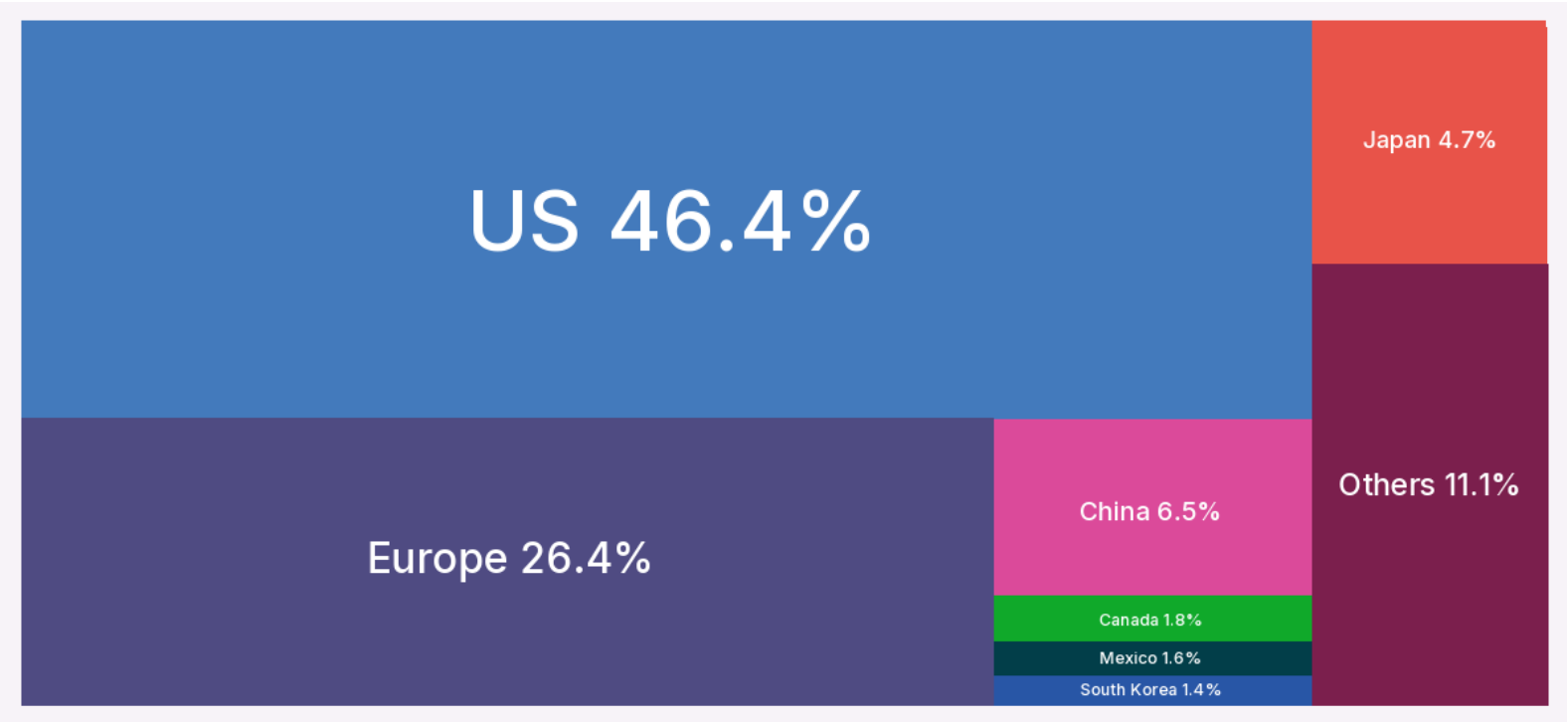


Figure 2: European medical device market growth rates based on manufacturer prices *(MTE facts and figures 2025)*

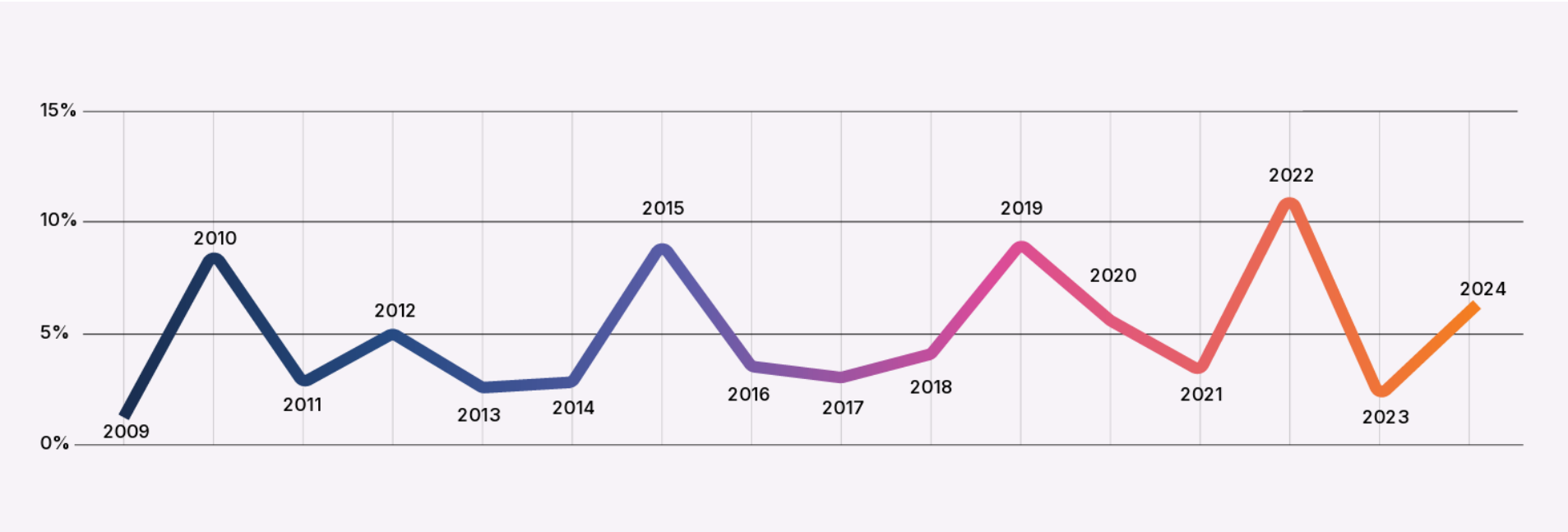


Figure 3: European IVD market growth rates based on manufacturer prices *(MTE facts and figures 2025)*

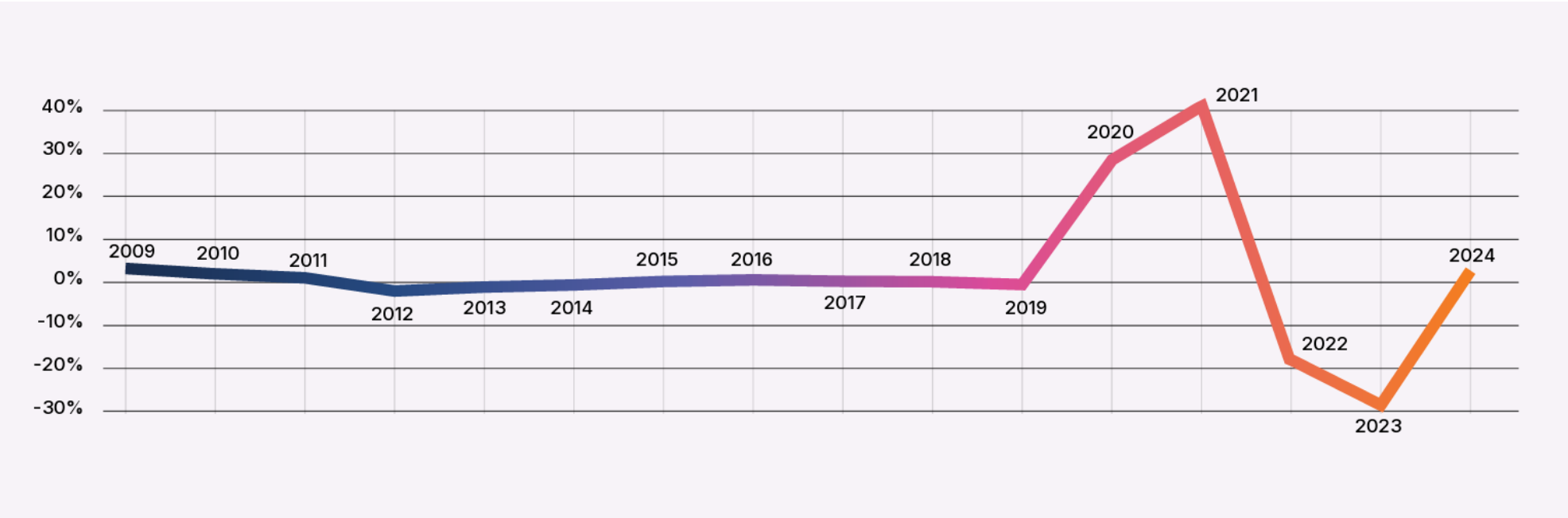


Table 4: Scoring of post-market surveillance, vigilance and market surveillance

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
How successful have the MDR and IVDR been in contributing to its general objectives in terms of: (a) ensuring a high level of protection of health for patients and users? To what extent has **post-market**	• Level of vigilance activities and harmonisation of approaches for manufacturer corrective actions across Member States • Level of vigilance activities by manufacturers • Level of market surveillance activities by Member States	• Post-market surveillance and vigilance activities have increased (>20% in MIRs, >30% in PSRs, and >1% in FSCAs, from 2017-2024) (NCA survey). • 15.3% (or 26/170) manufacturers indicated that the number of MIRs they submit has increased, and 23.5% (or 40/170) indicated that at least one MIR had led to a FSCA (PC). • 13.5% (or 23/170) manufacturers indicated that they had submitted	• >¾ (or 13/17) EU/non-EU citizens agree or strongly agree that devices are sufficiently monitored (0/17 disagree or strongly disagree), and almost ¾ (or 261/352) of stakeholders agree or strongly agree that safety issues are adequately identified and addressed when detected (PC). • 46.9% (or 15/32) healthcare providers agreed or strongly agreed that they were aware on how to report an incident with MDs, and 0% (0/14)	+ (positive)	• Only 16 EU MS + 1 EAA + 1 Customs Union country (18/30) responded to the NCA survey. • Most devices on the market are still legacy devices, yet there's an increase in reports of serious incidents. Difficult to assess whether any evolution observed reflects changes in device safety or reportability. • Duplication and overlapping of

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
surveillance and vigilance improved the detection and management of risks?		MIRs that, after further analysis, did not fulfil the vigilance reporting requirements (PC). • >8-fold increase in product samples controlled (NCA survey). • >25% increase in CEFs (NCA survey). • Inspections remain constant. However, <¼ of national inspection reports have a corresponding final inspection report (NCA survey).	agreed or strongly agreed with IVDs (PC). 6.5% (or 3/46) agreed or strongly agreed that they are reporting more safety issues now compared to 2017. • 130 entries to the CfE presented perspectives on PMS. Recurring themes included critiques of the excessive administrative burden, redundancy, and inefficiency of PMS requirements (CfE). • 21.5% of entries to CfE indicated that PMS requirements were overly burdensome and		reporting requirements and of assessment. • Coordination of NCA vigilance and market surveillance activities, and joint actions, are increasing. • Experience with market surveillance measures is starting. • EUDAMED's *Market Surveillance* module will only be available and mandatory to use from 28 May 2026, and the vigilance module will follow.

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
			disproportionate. Criticisms included excessive documentation, redundant reporting, and disproportionate requirements for low-risk or well-established devices (CfE). • 22 (16.9%) entries argued for a risk-based approach, with proposals including tailoring PMS to device risk class, market history, or safety profile (CfE). • 12 (9.3%) entries highlighted the need for petter integration of PMS with other regulatory processes (CfE).		

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
			• There is broad support for leveraging real-world data, streamlining reporting, and adopting risk-based approaches to reduce administrative burden (CfE). • Mixed perceptions on the legal clarity in post-market surveillance (32.9% agree or strongly agree, and 42.3% disagree or strongly disagree) and on the value of MCDG guidance documents (57.3% agree or strongly agree, and 45.8% disagree or strongly disagree) (PC).		

Evaluation question	Indicator(s)	Quantitative evidence	Qualitative evidence	Overall assessment (scale --/-/0/+/++)	Comments / data gaps
			• 149 vigilance coordination exchanges since 2021 among NCAs. • 3 market surveillance device safety task forces since 2021. • 21 Member States participate in JAMS 2.0, and 9 Member States participate in JACOP. • Most NCAs conduct market surveillance activities for devices offered by distance or online sales (66.6% or 12/18) (NCA survey).		

Table 5: Scoring of Simplification and streamlined procedures

Topic	Indicator(s)	Evidence	Overall assessment (scale --/-/0/+/++)	Comments/data gaps
Regulatory structure and coordination	• Governance and ways of working • Resources	• 275 responses to the Call for Evidence discuss challenges with the notified body system under the Regulations. Recurring themes included limited capacity, long delays, inconsistent interpretations of regulations, high costs, and lack of harmonisation across notified bodies (CfE). • 95 entries (34.5%) discussed problems related to inconsistencies in notified body practices were raised. These included variability in interpretations, timelines, costs, and requirements across notified bodies (CfE). • 88 entries (32.0%) discussed the need for centralised governance, standardised processes, and improved coordination (CfE). • Two notified bodies provided feedback calling for clearer guidance and streamlined processes (CfE). • One notified body acknowledged proposals for a single governance structure for notified body	- (negative)	• Data from the CfE and PP is in the form of open contributions. The study on governance was the only structured data collection exercise on this topic. • Governance is a perception-based topic • Lack of quantitative data due to difficulty to measure.

Topic	Indicator(s)	Evidence	Overall assessment (scale --/-/0/+/++)	Comments/data gaps
		designation and monitoring but warned that it could reduce competitiveness and increase costs while potentially impacting patient safety (CfE). • One survey found that only 6% of all companies working with notified bodies have no problems working with the notified body in question (PP). • Three manufacturer associations propose centralising notified body designation, among other tasks (PP). • One manufacturer association also cites '[i]nconsistent demands being placed on the notified bodies from each individual competent authority' (PP). • One position paper stated that 'Manufacturers experience a fragmented approach during the review of Technical Documentation and audits, resulting in inconsistencies in the assessment of conformity and compliance' (PP). • A health provider suggested that 'enhanced harmonisation and centralisation, would also		

Topic	Indicator(s)	Evidence	Overall assessment (scale --/-/0/+/++)	Comments/data gaps
		indirectly contribute to enhancing predictability for manufacturers and researchers alike and, thereby, fostering innovation.' (PP). • Of the respondents to the NCA survey (16 EU MS, 1 EEA, 1 Customs Union country), there were a total of 58 FTEs dedicated to EU-level coordination (NCA survey). • 28% of healthcare institutions, professionals or patient organisations, and 35% of economic operators or trade associations, agreed that the regulatory governance structure and the way of working are clear (governance study). • 32% of healthcare institutions, professionals or patient organisations, and 34% of economic operators or trade associations, agreed that collaboration among actors is good (governance study). • 33% of both national competent authorities and economic operators or trade associations, and 36% of healthcare institutions, professionals or		

Topic	Indicator(s)	Evidence	Overall assessment (scale --/-/0/+/++)	Comments/data gaps
		patient organisations, agreed that most issues with the governance structure were temporary and were likely to subside within the following 2-3 years (governance study).		
Predictability and proportionality	• Cost-efficiency of notified body certification • Timelines for certification • Requirements for low- and medium-risk devices • Well-established technologies	• The average cost of MDR recertification was EUR 45,748 for QMS certificates and EUR 35,104 for product certificates, as reported by EOs. • There are currently 12 well-established technologies. The current, on-going revision of this list has identified a further >50 potential candidates for WET designation. • Average cost of drawing up the clinical evaluation was EUR 105,654 (lowest: EUR 27,764 for Class Ir; highest: EUR 246,609 for Class III). • Classification disputes/decisions have decreased under the Regulations compared to the Directives. • The respondents to the NCA survey (16 EU MS, 1 EEA, 1 Customs Union country), indicated that	- (negative)	• Predictability is a perception-based topic • Lack of quantitative data due to difficulty to measure.

Topic	Indicator(s)	Evidence	Overall assessment (scale --/-/0/+/++)	Comments/data gaps
		they had received 349 consultation procedures for tissues or cells of animal origin or their derivatives; 7 for companion diagnostics (+ 24 to the EMA); 2 for substance-based devices; and 623 for ancillary substances incorporated in medical devices (+ 9 to the EMA). • Almost ¼ of NBs that had used structured dialogues experienced >25% reduction in time for conformity assessment (NB survey). • 198 entries (61.1%) highlight variability in interpretations by notified bodies and national authorities, leading to inefficiencies and unpredictability (CfE). • 112 entries (31.1%) discussed the disproportional impact of the Regulations on SMEs and start-ups. A NoBoCap report found innovation activities/projects for new devices declined with 59% for SMEs active in IVDs and 54% for SMEs active in MDs (CfE).		

Topic	Indicator(s)	Evidence	Overall assessment (scale --/-/0/+/++)	Comments/data gaps
		• 76 entries (23.9%) criticise the stringent requirements for low-risk devices, suggesting they do not align with actual safety risks (CfE). • 325 entries discussed the impact of the Regulations on SMEs, with 85.5% of these entries (278 entries) discussing the disproportionate financial and administrative burdens of the Regulations on SMEs. 67 entries (38.1%) highlighted that the MDR/IVDR disproportionately affects SMEs compared to larger companies, creating competitive disadvantages (CfE). • 132 entries (33.6%) discuss specific challenges for niche and orphan devices, with stakeholders highlighting the disproportionate impact of the Regulations (CfE). • 78 entries (36.7%) discussed the disproportionate requirements for clinical evidence, particularly in relation to low-risk and legacy devices (CfE).		

Topic	Indicator(s)	Evidence	Overall assessment (scale --/-/0/+/++)	Comments/data gaps
		• A manufacturer association reports that the attractiveness of Europe to be the first region for launching diagnostic innovations has decreased by 40% for large companies and 12% for SMEs (CfE). • 28 entries (21.5%) believe that PMS requirements are overly burdensome and disproportionate (CfE). • 98 entries (20.9%) discussed solutions related to proportionality and risk-based approaches, such as tailoring requirements to device risk levels, and reducing burdens for low-risk and legacy devices (CfE).		
Administrative burden	• Cost-efficiency of administrative costs • Reporting requirements	• <20% of respondents agreed that the administrative costs of complying with the Regulations are acceptable and will decrease once the Regulations are fully implemented (PC). • Several reporting obligations: Clinical Evaluation Plan (CEP), Clinical Evaluation Report (CER), Post-Market Clinical Follow-up	- (negative)	• Due to ongoing implementation, there is not a full overview of reporting requirements.

Topic	Indicator(s)	Evidence	Overall assessment (scale --/-/0/+/++)	Comments/data gaps
	• Documentation requirements	(PMCF) Plan, PMCF Evaluation Report, Post-Market Surveillance (PMS) Plan, PMS Report, Periodic Safety Update Report (PSUR) and Periodic Summary Report (PSR), Summary of Safety (and Clinical) Performance (SSCP), and Trend Report. • 13.5% (or 23/170) manufacturers indicated that they had submitted MIRs that, after further analysis, did not fulfil the vigilance reporting requirements (PC). • < ¼ of national inspection reports have a corresponding final inspection report (NCA survey). • Some PMS/Vig/MS activities are duplicated between notified bodies and NCAs. • 221 entries are related to administrative burdens, with 183 of these entries (82.8%) explicitly criticising the excessive administrative burdens and documentation requirements under the Regulations (CfE).		

Topic	Indicator(s)	Evidence	Overall assessment (scale --/-/0/+/++)	Comments/data gaps
		• 58 companies and 10 business associations indicate that the increased documentation and administrative requirements under the Regulations do not significantly enhance device safety (CfE). • According to a study conducted by a business association, approximately 60% of IVD and MD manufacturers find the administrative burden and associated costs the largest regulatory barriers for bring innovative products to market (CfE). • A health provider claimed that they would need up to 14 additional staff members to comply with Article 5(5) of the IVDR, highlighting the significant administrative burden placed on academic hospitals (CfE). • In position papers, manufacturers emphasize the disproportionate impact of administrative burden on SMEs and innovation, while healthcare professionals and insurers prioritise transparency and data accessibility (PP).		

Topic	Indicator(s)	Evidence	Overall assessment (scale --/-/0/+/++)	Comments/data gaps
Digitalisation	• Electronic instructions for use (e-IFU)	• At a survey to healthcare professionals, 88% of respondents preferred e-IFUs compared to the paper version. 61% agreed that e-IFUs should be expanded to all medical devices, and a further 29% supported a limited expansion to devices where a healthcare professional trains the lay user. • 46 entries (20.8%) advocate for digitalisation and streamlined processes to reduce administrative burdens (CfE). • A business association proposed the formal requirements (such information on application filings to a notified bodies) could benefit from being more process oriented and further digitalisation (CfE).	0 (neutral)	• Digitalisation is an evolving field which was not a priority of the Regulations when they were adopted. • Limited quantitative data available.

Table 6: Overall evaluation table

Evaluation criterion	Section / Sub-area	Summary of findings	Score (--/–/0/+/++)
Effectiveness	Section 4.1.1.1. Legal certainty, transparency and trust	• **Legal certainty:** Mixed. Fewer formal disputes and > 100 MDCG guidance docs, but stakeholders (CfE, PC) still perceive ambiguity and incoherence. • **Transparency:** Negative. EUDAMED incomplete, SSCPs limited, <50% of PC respondents agreed MDR/IVDR improved transparency. • **Trust:** Negative. CfE and PC show confidence not improved; ~56% of PC respondents disagree/strongly disagree that MDR/IVDR increased trust.	–
	Section 4.1.1.2. Notified bodies, conformity assessments and clinical evidence	• **Resources**: Mixed. NBs and FTEs have continuously increased. >30% FTEs dedicated to administrative and supporting tasks (NB survey). • **Designation**: Positive. Designation times have decreased. >90% of codes applied for are obtained, but there is low coverage for some codes (EC, internal sources). • **Oversight**: Negative. Not coordinated/harmonised. Divergent approaches/interpretations without effective central control (PC, CfE, PP). • **Conformity assessment**: Negative. New certificates take 6-18 months (QMS only) and 13-24 months (QMS and product). 50% time spent with manufacturer. Time and costs are seen as barriers (PC, CfE, PP). • **Clinical evidence**: Mixed. Data gathering has increased, and expert panels have been established, but evaluations are incomplete and not available (PC, PP).	–
	Section 4.1.1.3. Market functioning and level playing field	• **Market functioning**: Mixed. Compared to 2017, the overall market is larger and more resilient, with long-term average annual growth of 6% for MD and 4.3% for IVD, however no direct translation proportional increase in innovation and competitiveness.	–

Evaluation criterion	Section / Sub-area	Summary of findings	Score (--/–/0/+/++)
		• **Innovation**: Negative. Broad consensus across stakeholders (PP, CfE) that the current regulatory framework hinders innovation, particularly for SMEs, start-ups, and niche markets. >85% of PC respondents believe that the Regulations dd not contribute to innovation in the medical device sector in the EU. • **Competitiveness**: Negative. Stakeholders (governance study) state that due to the regulatory barriers, EU-based manufacturers seek market access/certification outside the EU. >80% of PC respondents believe that the Regulations did not contribute to competitiveness in the medical device sector in the EU. • **Level playing field**: Negative. Consensus among stakeholders (CfE, PP) that inconsistencies in the interpretation and implementation of the Regulations across MS and NB create an uneven playing field. >75% of PC respondents disagree that the Regulations contributed to an even playing field for EOs. • **Availability**: Negative. 65% of governance study respondents consider that the current regulatory framework contributes to little or not at all to the availability of devices for patients and users. Difficult to estimate the % of transitioned devices from Directives to Regulations.	
	Section 4.1.1.4. Post-market surveillance, vigilance and market surveillance	• **Reporting**: Mixed. Increased capacity to detect safety risks, but increased burden for economic operators (CfE, PC, PP). Duplication: of reports for EOs & of activities between NCAs and NBs. • **Coordination**: Positive. Increasing coordination and actions. EUDAMED not available yet or mandatory is a limitation.	+

Evaluation criterion	Section / Sub-area	Summary of findings	Score (--/–/0/+/++)
		• **Perceptions**: Positive. Stakeholders agree that devices are sufficiently monitored, and safety issues are adequately identified and addressed (PC). Evaluation complicated by predominance of legacy devices currently on the market.	
	Section 4.1.1.5. Simplification and streamlined procedures	• **Governance:** Mixed. Increased complexity, which requires extra coordination and resources. • **Predictability & Proportionality:** Negative. The system is perceived as unpredictable and disproportionate, particularly towards lower-risk devices. • **Administrative burden:** Negative. Reporting obligations have increased without necessarily bringing intended added value for safety in all some areas. • **Digitalisation:** Mixed. e-IFU has been expanded.	–
Efficiency	Section 4.1.2.1. Manufacturers (large & SMEs)	• **Costs:** Strong Negative. Industry representatives identify clinical evidence requirements, certification costs and administrative burdens as significant cost drivers, with implications such as product withdrawals and increased allocation of resources. • **Benefits:** Positive. Stakeholders acknowledge the potential for the Regulations to provide greater predictability and legal certainty, reputational gains and better market across through harmonisation. Benefits not yet fully realised however, ambiguity and inconsistent application remain a stakeholder concern.	0
	Section 4.1.2.2. Importers/distributors	• **Costs:** Mixed. While average yearly compliance costs for importers and distributers vary widely under the Regulations, with some reporting zero additional costs, others face significant financial burdens associated with verification checks.	0

Evaluation criterion	Section / Sub-area	Summary of findings	Score (--/–/0/+/++)
	Section 4.1.2.3. Notified bodies	• **Costs:** Negative. Notified bodies have faced resource-intensive costs due to designation processes, extensive documentation, and coordination with national authorities. • **Benefits:** Strong positive. The Regulations have resulted in increased revenues for notified bodies due to higher fees charged for certificate issuance and maintenance, positioning certification as a core revenue stream.	0
	Section 4.1.2.4. National Competent Authorities	• **Costs:** Negative. National competent authorities have experienced significant (though expected) increases in human resource needs and IT infrastructure investments to manage the new regulatory tasks and coordination efforts, disproportionately straining smaller authorities' budgets and staff. • **Benefits:** Positive. NCAs have gained a more central role in the harmonized market oversight, with clearer responsibilities and a stronger mandate for intervention.	0
	Section 4.1.2.5. Health Providers	• **Costs:** Negative. Health institutions bear administrative burdens and significant compliance costs under the Regulations, impacting research and patient care. • **Benefits:** Positive. Despite the costs, health providers acknowledged improved safety assurance and clinical evidence requirements, along with anticipated gains in transparency through Eudamed.	0
	Section 4.1.2.6. Patients and Users	• **Costs:** Negative. Patients face indirect costs through reduced device availability and delays in innovative product certification, particularly affecting individuals affected by rare diseases, paediatric conditions, and vulnerable groups.	0

Evaluation criterion	Section / Sub-area	Summary of findings	Score (--/–/0/+/++)
		• **Benefits:** Positive. Patient organisations and consumer groups acknowledge strengthened regulatory frameworks through stricter clinical and performance requirements, enhanced post-market surveillance and traceability, and increased transparency.	
	Section 4.1.2.7. EU-level Governance	• **Costs:** Negative. The governance structure faces substantial IT development and maintenance costs, alongside significant resource investments for regulatory coordination, guidance development, and expert panel support. • **Benefits:** Positive. The reinforced governance system at the EU level is enhancing regulatory harmonisation, maintaining the EU's global leadership in the medtech sector.	0
Coherence	Internal coherence	Mixed. No major issues identified, however inconsistencies remains, such as relating to terminology and requirements between the Regulations and Annexes, with specific issues like undefined key terms contributing to uncertainty despite a high percentage of similar provisions.	0
	External coherence	Mixed. While the Regulations align with broader EU health policy objectives and contribute to international cooperation via IMDRF, consulted stakeholders report low agreement on their alignment with other EU legislations, with ongoing challenges in integrating newer frameworks and international guidance.	0
Relevance	–	Mixed. While the Regulations remain relevant for ensuring patient safety and transparency, particularly through stringent requirements and tools like EUDAMED and UDI, stakeholders question their long-term effectiveness in promoting innovation, competitiveness, and harmonised market functioning, highlighting concerns about implementation challenges and disproportionate impacts on SMEs.	0

Evaluation criterion	Section / Sub-area	Summary of findings	Score (--/–/0/+/++)
EU Added Value	–	Mixed. The Regulations provide significant added value by establishing a unified legal framework enhancing safety, surveillance, and vigilance, preventing inconsistencies in patient protection across Member States. However, persistent divergences in interpretation and implementation hinder realisation of intended benefits, with varying efficiency and proportionality in cost impacts across stakeholders.	0

ANNEX VII. EXPLANATORY DIAGRAMS

Figure 1. Governance structure (*source: European Commission, internal*)

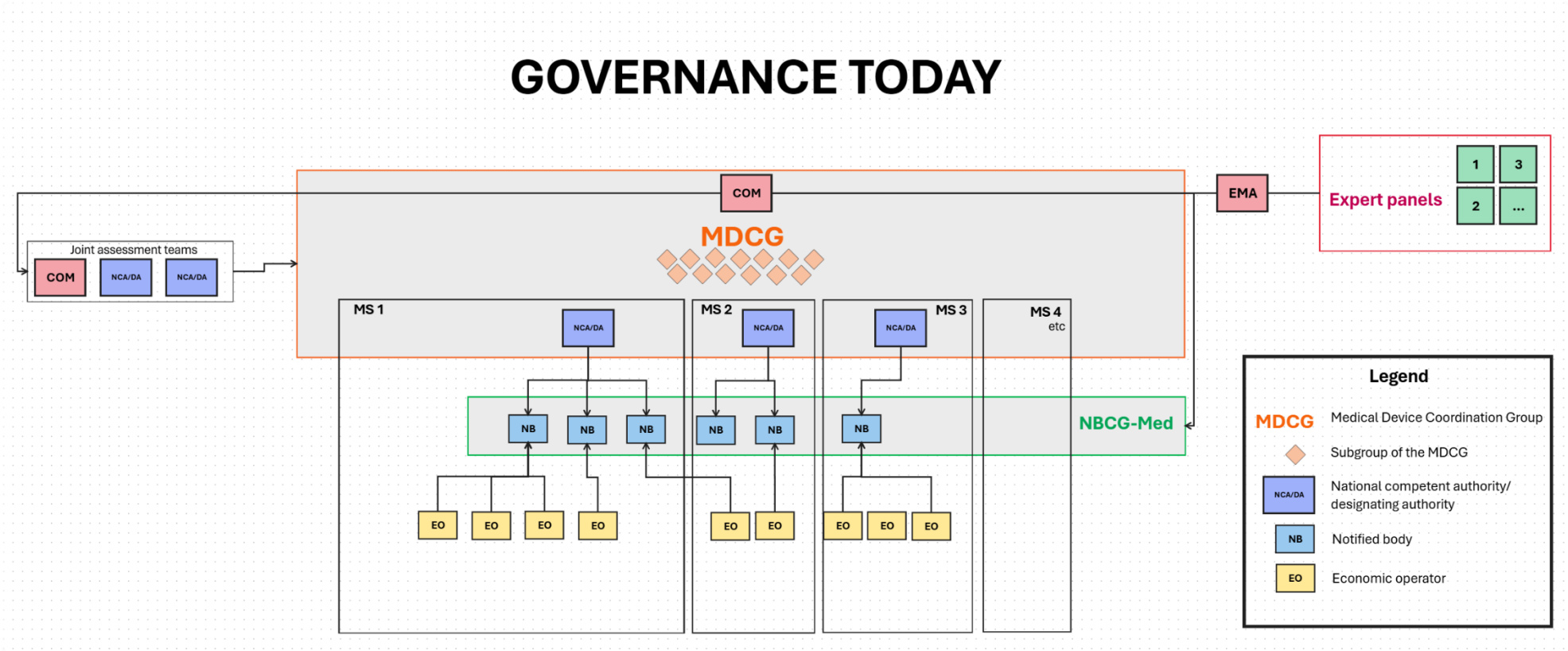
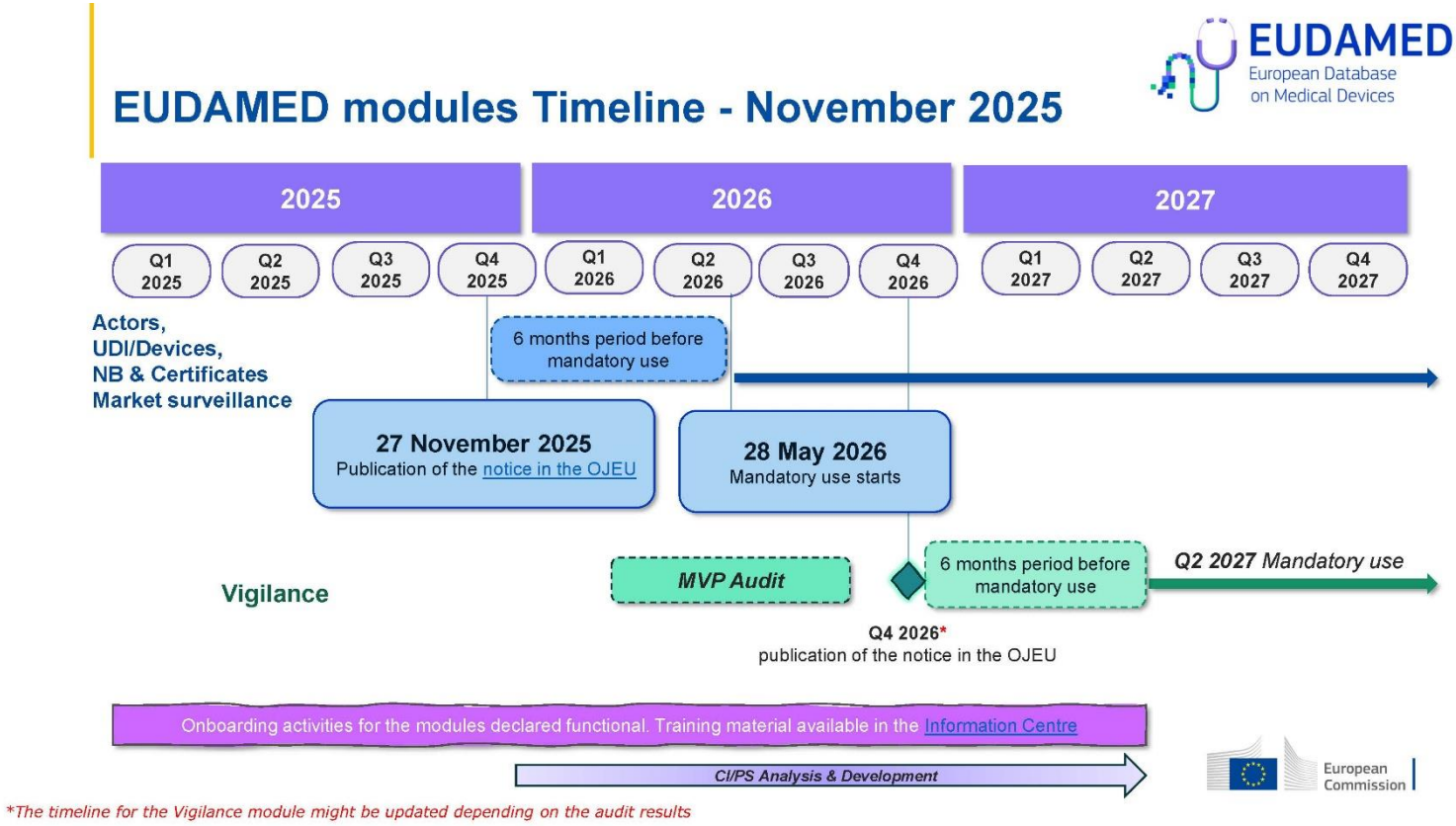


Figure 2. EUDAMED timeline (*source: European Commission website*)



The 4 first modules (below as quoted in the Commission Decision (EU) 2025/2371) will be mandatory to use from 28 May 2026, 6 months after the publication of the notice in the OJEU, in accordance with the transitional provisions set out in Regulation (EU) 2024/1860.[341]

a) **Actor module -** the electronic system on registration of economic operators referred to in Article 30 of Regulation 2017/745 and Article 27 of Regulation (EU) 2017/746;
b) **UDI/devices module -** the UDI database and the electronic system for registration of devices referred to in Articles 28 and 29 of Regulation (EU) 2017/745 and Articles 25 and 26 of Regulation (EU) 2017/746;
c) **Notified bodies & Certificates module -** the electronic system on notified bodies and certificates referred to in Article 57 of Regulation (EU) 2017/745 and Article 52 of Regulation (EU) 2017/746;
d) **Market Surveillance module -** the electronic system on market surveillance referred to in Article 100 of Regulation (EU) 2017/745 and Article 95 of Regulation (EU) 2017/746.

The 3 first are already available on voluntary basis; Actor since December 2020; UDI/Devices and NBS & certificates since October 2021.

The 2 remaining modules have the following status:

- **Vigilance and post-market surveillance –** audit planned for mid-2026
- **Clinical Investigations and performance studies –** under development

[341] See note 63, pg 13.

Figure 3. Median number of days for notified body designation under MDR/IVDR (*source: European Commission, internal*)

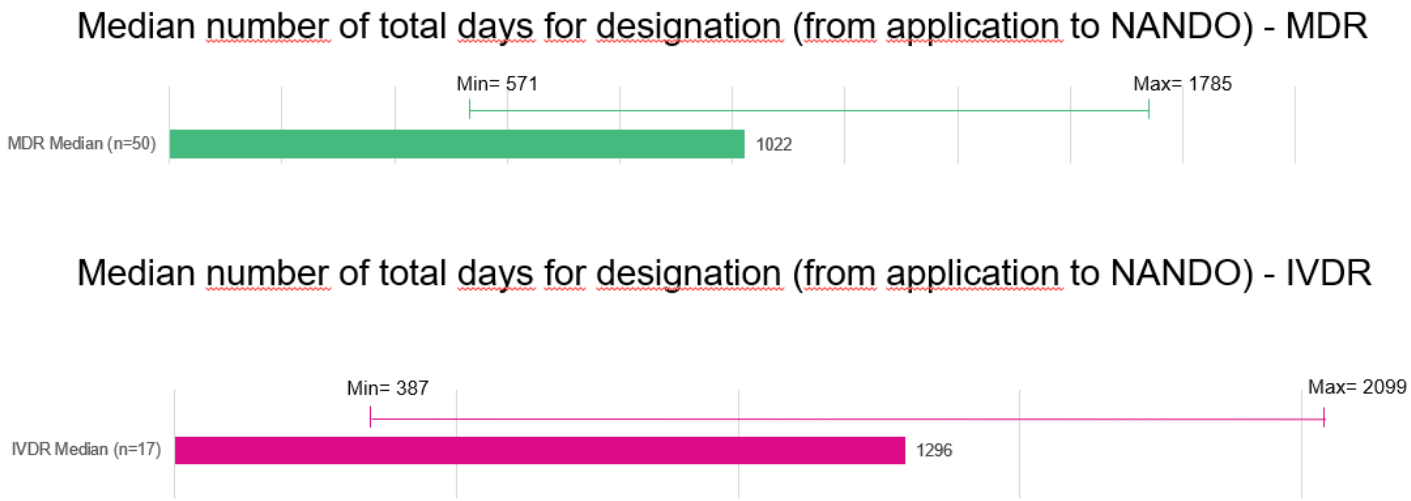
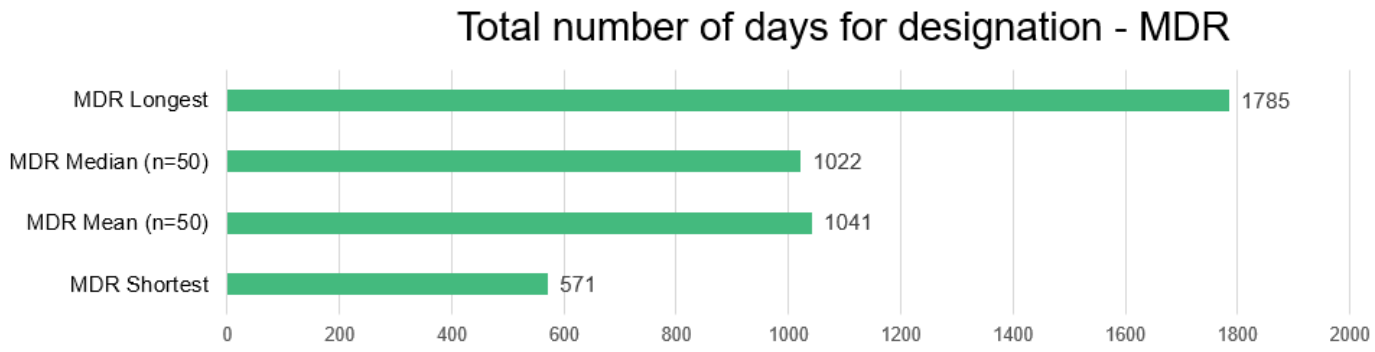


Figure 4. Total number of days for notified body designation under MDR/IVDR (*source: European Commission, internal*)



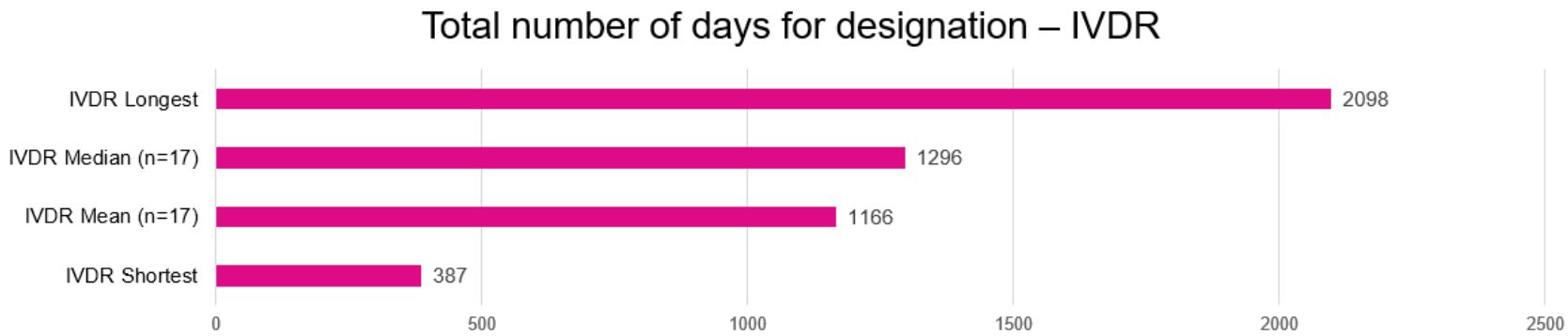
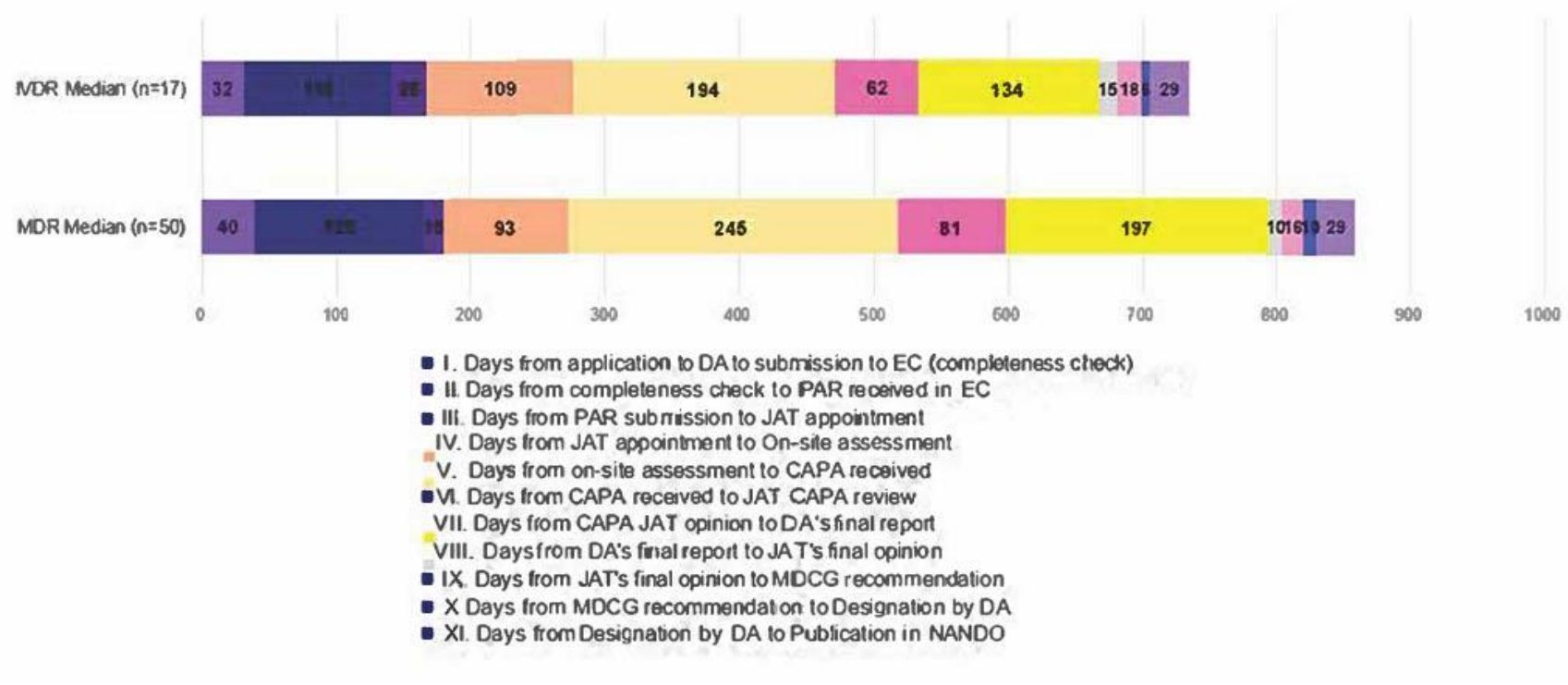


Figure 5. Median number of days for each milestone of the notified body designation process (*source: European Commission, internal*)



DA – Designating Authority
CAPA – Corrective and Preventative Action
EC – European Commission
JAT – Joint assessment team
NANDO – New Approach Notified and Designated Organisations Information System
PAR – Preliminary assessment review

Figure 6. Evolution of the number of notified bodies under the MDD/AIMDD and MDR (*source: European Commission, internal*)

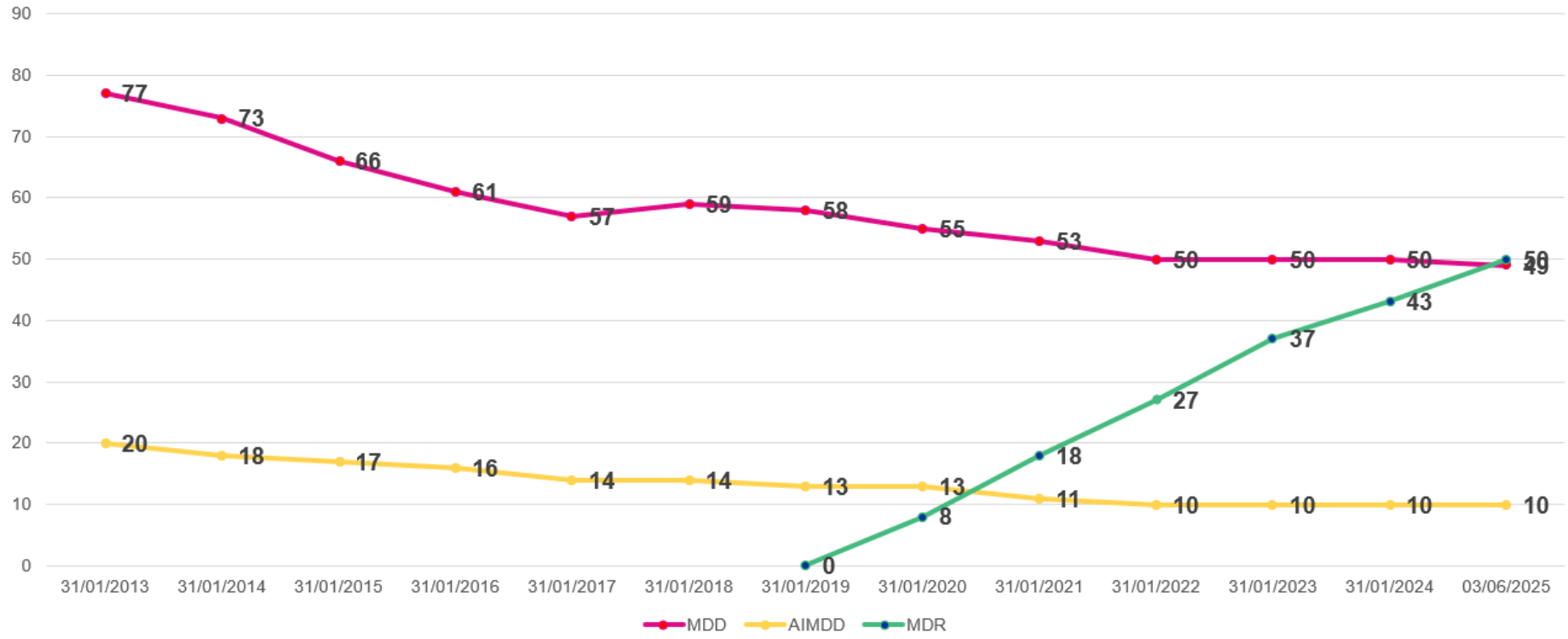


Figure 7. Risk classification of medical devices (*source: European Commission, internal*)

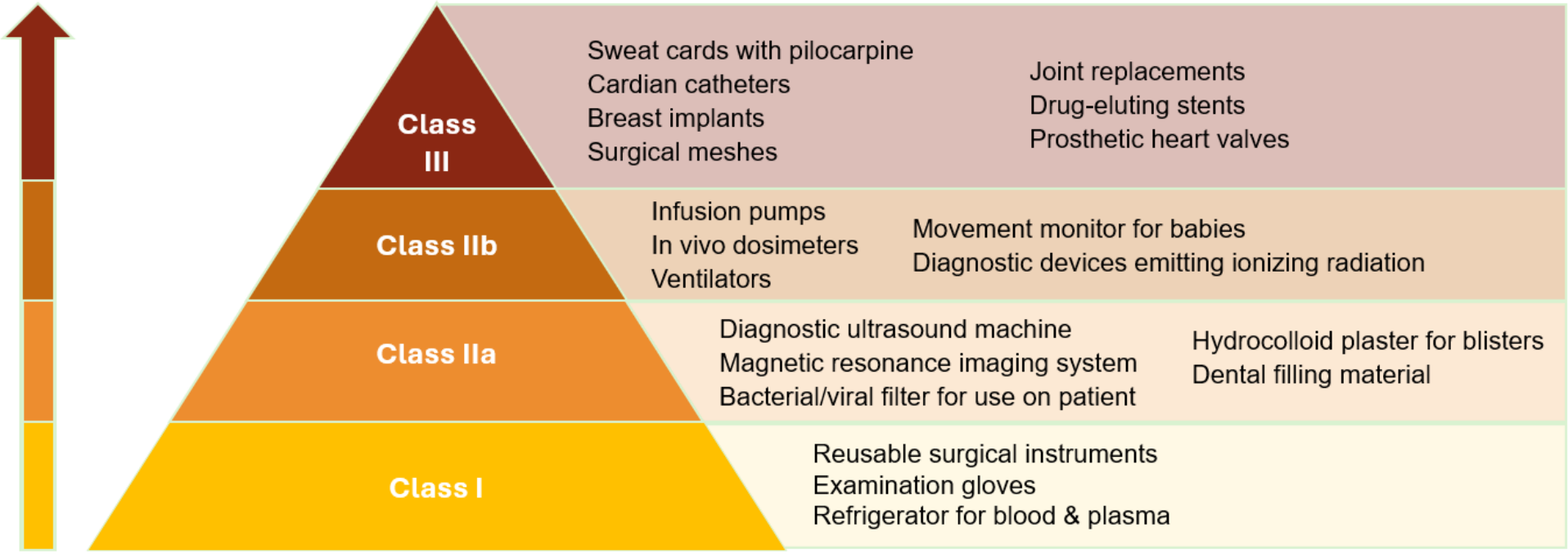
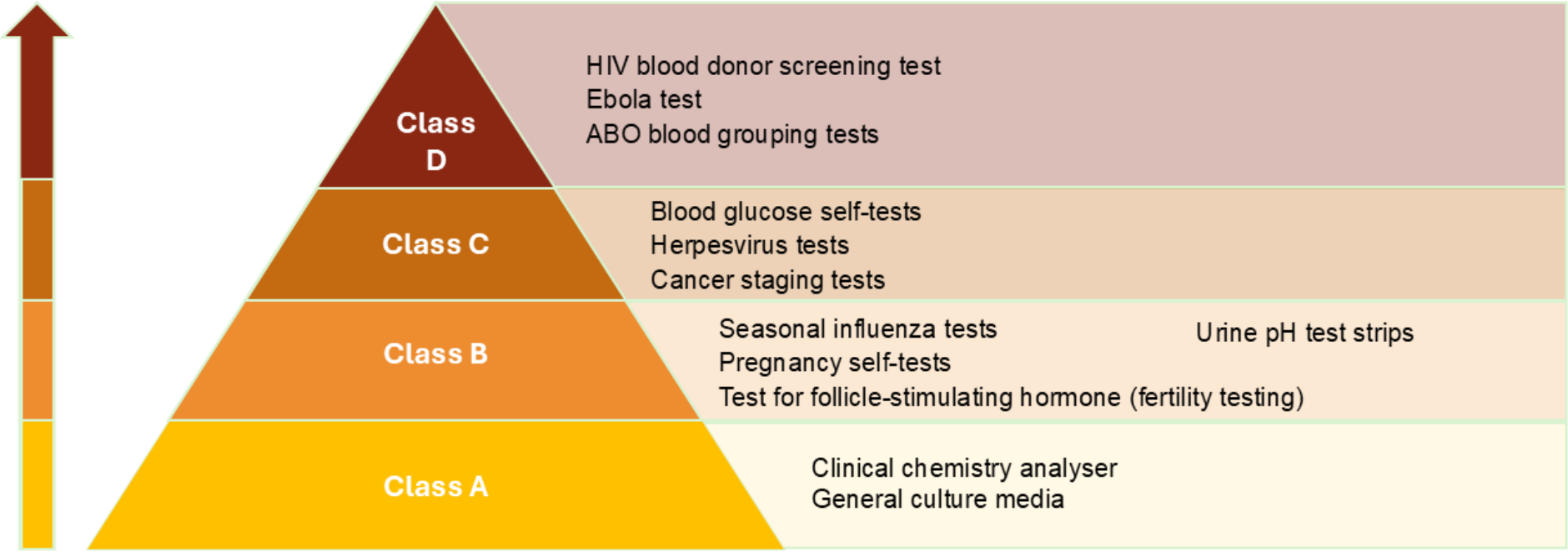


Figure 8. Risk classification of in vitro diagnostics (*source: European Commission, internal*)



ANNEX VIII. STAKEHOLDER MAPPING

(*Source: based on Technopolis report*[342])

Stakeholder group	Influence	Interest	Expertise of group / reasoning	Corresponding general user type (in surveys, public consultation)
European Commission and EU bodies, including the EMA	High	High	These bodies are central in coordinating the implementation of EU-level regulation and cross-border consistency – institutional and strategic role.	N/A
EU MS competent authorities for medical devices	High	High	These authorities are directly responsible for national implementation, monitoring and enforcement of the MDR/IVDR. They shape national policies and procedures and contribute to shaping EU-level policies and direction.	EU/EEA public authority
EU reference laboratories	High	High	The EU reference laboratories (EURL) conduct evaluations of IVDs to support conformity assessments of these devices. This involves the laboratory testing of the performance claims made	N/A

[342] See note 25, pg 7.

			by the manufacturer and the device's compliance with safety and performance standards. The EURLs are a key component of the testing around IVDs , issuing a scientific opinion to the notified body on devices as requested and upholding the standards for IVDs in the European Union.	
Large EU based manufacturers developing, manufacturing, and placing medical devices on the market, and/or associations representing this group	High	High	These groups are heavily affected by regulatory compliance requirements and contribute to discussions at EU level on MDR/IVDR implementation.	Economic operator (Art 2(35) MDR / Art 2(28) IVDR)
Notified bodies	High	High	These bodies perform conformity assessments and issue related certifications, essential to establishing market access for medical devices.	Notified body designated under MDR/IVDR (Art 2(42) MDR / Art 2(34) IVDR)
EU Authorised Representatives	Medium	High	EU Authorised Representatives act on behalf of non-EU manufacturers.	Economic operator (Art 2(35) MDR / Art 2(28) IVDR)
Healthcare professionals, and institutions, and/or associations representing	Medium	High	These groups use medical devices for the care and treatment of patients. They have an interest in the practical use and safety of these devices. They may have	Healthcare professionals / Healthcare professional associations

this group (e.g. medical or clinical associations)			specific obligations under the MDR/IVDR if they manufacture, modify or reprocess devices within their institution. They also have reporting requirements for incidents or adverse events in the use of medical devices. However, they do not participate in assessments of those elements and are often not involved in regulatory policy-making in a structured manner.	
EU based SMEs and start-ups developing, manufacturing, and placing medical devices on the market	Medium	High	Similar to large manufacturers, these groups are also highly impacted by compliance costs but generally are less represented at EU level discussions. These types of manufacturers may be underrepresented in data and evaluation of these Regulations, possibly due to limited resources to participate in European discourse.	Economic operator (Art 2(35) MDR / Art 2(28) IVDR)
International and European standardisation bodies	Medium	High	These organisations are relevant for development of standards on health, safety and performance of medical devices, as well as on quality and risk management, packaging etc. In particular, European standardisation organisations (CEN and CENELEC)	N/A

			play an essential role in adopting harmonised European standards, as specifically requested by the Commission in its decision-making process, mostly on the basis of standards developed by international standardisation organisations (ISO and IEC). Once received and assessed by the Commission, harmonised European standards are cited in the Official Journal of the European Union (OJEU) to provide presumption of conformity with the requirements of the Regulations. This is very useful for manufacturers for conformity assessment procedures on their devices, as well as for notified bodies and competent authorities in charge of market surveillance.	
Importers and distributors of medical devices in the EU, and/or associations representing this group	Medium	High	These organisations have specific obligations under the MDR/IVDR.	Economic operator (Art 2(35) MDR / Art 2(28) IVDR)
Insurers, and/or associations representing this group	Medium	High	Insurers have a strong interest in the price and type of medical devices on the market. They have a strong influence on	N/A

			which products are reimbursed at national level, access to these products, and healthcare provider behaviour, but less so in regulatory policymaking. Their degree of influence can be affected by the type of insurance systems in specific EU Member States.	
National healthcare systems, including Ministries of Health, public health bodies, and publicly funded providers[100]	Medium	High	National healthcare systems have a strong interest in the practical use and safety of these devices. However, these bodies are often indirectly involved in the upholding of standards around the safety, quality and performance of medical devices, relying on other bodies in the national or European sphere.	EU/EEA public authority
Regulatory affairs experts active in the medical devices field, and/or associations representing this group	Medium	High	Often closely linked to manufacturers and influence implementation and compliance practices, with high technical input and interest.	N/A
System/procedure pack producers (SPPP), and/or associations representing this group	Medium	High	SPPPs have specific obligations under the MDR/IVDR.	Economic operator (Art 2(35) MDR / Art 2(28) IVDR)
General public, patients and consumers,	Medium	High	The ultimate end-users are directly affected by safety, efficacy,	EU citizen, non-EU citizen, patient organisation

associations representing them (e.g. patient organisations)			transparency and costs, but their influence is limited and indirect. Patient associations contribute to discussions at EU level.	
International intergovernmental organisations and other international associations	Medium	Medium	These organisations are relevant for regulatory convergence and reliance but have no formal power over EU decision-making.	N/A
Large non-EU manufacturers developing, manufacturing, and placing medical devices on the market	Medium	Medium	These organisations have a high compliance burden and must appoint EU Authorised Representatives in order to place their products on the EU market, and whilst are not formally/specifically involved in regulatory discussions in the EU, may be represented by EU manufacturer associations.	Economic operator (Art 2(35) MDR / Art 2(28) IVDR)
Non-EU/EEA countries	Medium	Medium	Non-EU Member States have no formal say in EU legislative processes, however may practice reliance on and/or have trade considerations affected by the MDR/IVDR. Indeed their frameworks and practices may indirectly influence EU policy making in the interests of international convergence in the field.	Non-EU/non-EEA public authority

Clinical investigators	Low	High	Clinical investigators of medical devices must adhere to the ethical and regulatory standards.	Healthcare professionals / Healthcare professional associations
Digital health, software and AI-tech developers	Low	High	Digital health and AI are becoming increasingly relevant under the MDR/IVDR, especially with medical software being classified as a medical device and the resulting need to comply with the requirements set out in these Regulations. They are not always formally/specifically represented in consultations but may be represented by existing manufacturer associations and are an emerging group with growing interest and moderate influence in the industry.	Economic operator (Art 2(35) MDR / Art 2(28) IVDR)
Ethics committees	Low	High	Ethics committees review clinical investigation/performance study applications. Given these committees are run at national level and report to the national competent authorities, their influence at EU level is limited.	N/A
Non-EU SMEs and start-ups developing, manufacturing, and	Low	High	Similar to large, non-EU manufacturers, these organisations have a high compliance burden and must appoint EU Authorised Representatives in order to	Economic operator (Art 2(35) MDR / Art 2(28) IVDR)

placing medical devices on the market			place their products on the EU market. They are not directly involved in EU regulatory discussions, and may further be constrained by financial, human and knowledge resources available to them.	
Other civil society organisations (CSOs)	Low	High	CSOs bring ethical and social perspectives and represent (vulnerable) groups or themes, however, their institutional influence is limited. Examples include groups focusing on consumer protection, environmental protection, digital and privacy rights, and/or labour or workers' rights.	Non-governmental organisation (NGO)
Independent experts from academic and research institutes active in medical devices	Low	Medium	Experts contribute evidence and expert analysis through publications, which may contribute to policy-making in an indirect fashion. They may also participate in policy and regulatory discussions, but this remains indirect influence which is often unstructured and in difficult-to-enter spheres.	Academic/research institution