Reports of Cases

JUDGMENT OF THE COURT (Sixth Chamber)

2 July 2026*

(Reference for a preliminary ruling – Medical devices – Regulation (EU) 2017/745 – Obligations of distributors before making a device available on the market – Identification wristbands intended to be worn by patients in the healthcare sector – No CE marking and no EU declaration of conformity – Concept of 'medical device' – Concept of 'intended purpose')

In Case C-427/24,

REQUEST for a preliminary ruling under Article 267 TFEU from the Landgericht Bochum (Regional Court, Bochum, Germany), made by decision of 28 May 2024, received at the Court on 18 June 2024, in the proceedings

Zentrale zur Bekämpfung unlauteren Wettbewerbs Frankfurt am Main eV

v

Diagramm Halbach GmbH & Co. KG,

intervener:

ZEBRA Technologies Europe Limited,

THE COURT (Sixth Chamber),

composed of I. Ziemele, President of the Chamber, A. Kumin (Rapporteur) and M. Bošnjak, Judges,

Advocate General: D. Spielmann,

Registrar: A. Calot Escobar,

having regard to the written procedure,

after considering the observations submitted on behalf of:

– Zentrale zur Bekämpfung unlauteren Wettbewerbs Frankfurt am Main eV, by M. Zain, Rechtsanwalt,

* Language of the case: German.

– Diagramm Halbach GmbH & Co. KG, by C. Göttschkes, Rechtsanwalt,

– ZEBRA Technologies Europe Limited, by M. Ottermann and O. Rathje, Rechtsanwälte,

– the European Commission, by T.S. Bohr and A. Spina, acting as Agents,

having decided, after hearing the Advocate General, to proceed to judgment without an Opinion,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 2(1) and (12) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ 2017 L 117, p. 1).

2 The request has been made in proceedings between Zentrale zur Bekämpfung unlauteren Wettbewerbs Frankfurt am Main eV (Centre for Protection against Unfair Competition, Frankfurt am Main, Germany; 'Zentrale'), an association combating unfair commercial practices, and Diagramm Halbach GmbH & Co. KG ('Diagramm'), a company marketing printed products which it produces itself and other products, concerning, inter alia, cessation of the marketing, by Diagramm, of identification wristbands intended to be worn by patients in the healthcare sector ('*Patientenarmbänder*') and manufactured by ZEBRA Technologies Europe Limited ('Zebra'), as long as those wristbands do not meet the requirements of Regulation 2017/745.

Legal context

European Union law

3 Article 2 of Regulation 2017/745, entitled 'Definitions', is worded as follows:

'For the purposes of this Regulation, the following definitions apply:

(1) "medical device" means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

– diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

– diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

– investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

– providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

devices for the control or support of conception;

products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

…

(12) "intended purpose" means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation;

…

(44) "clinical evaluation" means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer;

…'

4 Article 14 of that regulation, entitled 'General obligations of distributors', provides:

'1. When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.

2. Before making a device available on the market, distributors shall verify that all of the following requirements are met:

(a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;

…'

German law

5 The Gesetz gegen den unlauteren Wettbewerb (Law against Unfair Competition) of 3 July 2004 (BGBl. 2004 I, p. 1414), in the version applicable to the facts in the main proceedings ('the UWG'), is intended to protect competitors, consumers and other market participants against unfair commercial practices and to protect the public interest by ensuring undistorted competition.

6 Paragraph 3 of the UWG prohibits unfair commercial practices.

7 Under Paragraph 3a of that law, entitled ‘Infringement of the law’:

‘A person who infringes a statutory provision that is also intended to regulate market behaviour in the interests of market participants shall be regarded as acting unfairly where the infringement is liable to have a perceptible adverse effect on the interests of consumers, other market participants or competitors.’

8 Paragraph 5a of the UWG, entitled ‘Misleading conduct by omission’, provides:

‘(1) A person shall also be regarded as acting unfairly where he or she misleads a consumer or other market participant by withholding from him or her material information

1. which the consumer or other market participant requires, depending on the circumstances, in order to take an informed transactional decision and

2. the withholding of which is liable to cause the consumer or other market participant to take a transactional decision that he or she would not have taken otherwise.

(2) The following shall also be regarded as omission:

1. the withholding of material information,

2. the provision of material information in an unclear, unintelligible or ambiguous manner, and

3. the provision of material information in an untimely manner.

…

(4) A person shall also be regarded as acting unfairly where he or she does not indicate the true commercial intent of a transaction …’

9 Paragraph 8 of the UWG, entitled ‘Cessation of conduct and prohibitory injunction’, provides:

‘(1) Any commercial practice which is prohibited under Paragraph 3 or Paragraph 7 may give rise to an order to cease and desist, and, if there is a risk of recurrence, a prohibitory injunction. The right to obtain a prohibitory injunction shall be deemed to arise as soon as there is a risk of infringement of Paragraph 3 or Paragraph 7.

…

(3) The rights under subparagraph 1 shall be conferred on:

…

2. associations with legal personality seeking to promote commercial or independent professional interests which are included in the list of qualified trade associations referred to in Paragraph 8b [of the UWG] where they comprise a significant number of members that are entrepreneurs supplying goods or services of the same or a similar nature on the same market and the infringement affects the interests of their members;

…’

10 Paragraph 8b of the UWG, entitled ‘List of qualified trade associations’, provides, in subparagraph 1 thereof, that the Bundesamt für Justiz (Federal Office of Justice, Germany) is to maintain a list of qualified trade associations, which it is to publish on its website.

11 Paragraph 13 of the UWG, entitled ‘Written warning notice; obligation to cease and desist; liability’, provides, in subparagraph 3 thereof, that, where a written warning notice is justified and meets the requirements set out in Paragraph 13(2) of that law, the entity issuing the written warning notice may demand reimbursement of any necessary costs from the entity issued with the notice.

The dispute in the main proceedings and the questions referred for a preliminary ruling

12 In June 2023, Diagramm sold and supplied to a German nursing service two types of identification wristbands intended to be worn by patients in the healthcare sector, inter alia in hospitals (‘*Patientenarmbänder*’), which differed from one another solely in the printing technique used during their manufacture. More specifically, they were wristbands manufactured from a thermoplastic resin, which can be printed individually with letters, digits and/or a barcode in order to identify the patient and to save other data relating to him or her.

13 In a promotional document provided by Zebra, the producer of those wristbands, it was stated, inter alia, that the identification of patients using those identification wristbands could improve patient safety, particularly in the areas of medication, performance of tests and procedures, blood transfusions and sample collection. Before making the identification wristbands available on the market, Diagramm did not verify that they had been CE marked and that the EU declaration of conformity of those wristbands had been drawn up.

14 Zentrale, which is a qualified trade association within the meaning of Paragraph 8(3)(2) of the UWG and has been included in the list provided for under Paragraph 8b of the UWG, therefore considers that Diagramm has failed to fulfil its obligations under Article 14(1) and (2)(a) of Regulation 2017/745. Zentrale thus issued a written warning notice to Diagramm, ordering it to cease placing the patient identification wristbands at issue in the main proceedings on the market without the CE marking and without having drawn up an EU declaration of conformity in respect of them, and to give an undertaking to cease and desist (‘*Unterlassungserklärung*’). As Diagramm did not comply with that notice, Zentrale applied to the referring court, the Landgericht Bochum (Regional Court, Bochum, Germany), for an injunction and reimbursement of the costs associated with the written warning notice, on the basis of Paragraphs 3 and 3a of the UWG.

15 The parties to the main proceedings disagree as to whether or not the patient identification wristbands at issue in the main proceedings are to be classified as ‘medical devices’, within the meaning of Article 2(1) of Regulation 2017/745, and, consequently, whether the promotional information relating to those wristbands indicates an ‘intended purpose’, within the meaning of Article 2(12) of that regulation.

16 Zentrale submits that the patient identification wristbands at issue in the main proceedings, due to the way in which they are advertised by their manufacturer, Zebra, serve – at the very least in combination with other products – to monitor, diagnose and treat patients' diseases, injuries or disabilities. It argues that they accordingly perform an assistive function and should therefore be classified as 'medical devices' within the meaning of Article 2(1) of Regulation 2017/745.

17 Diagramm contends, by contrast, that the patient identification wristbands at issue in the main proceedings have no medical purpose. It maintains that their sole function is to clearly identify the patient within the hospital environment and that they therefore perform a purely administrative function, without being associated with the provision of any specific therapeutic or diagnostic service to the patient. According to Diagramm, the condition relating to the 'principal intended action … in or on the human body' laid down in Article 2(1) of Regulation 2017/745 has therefore not been satisfied.

18 The referring court, sharing the doubts of Diagramm and Zebra as to whether it is possible to classify the patient identification wristbands at issue in the main proceedings as 'medical devices', considers that the point of law relating to the interpretation of the provisions of Regulation 2017/745 has not yet been addressed in the case-law of the Court and that it is relevant to the adjudication of the dispute in the main proceedings.

19 In those circumstances, the Landgericht Bochum (Regional Court, Bochum) decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Does the advertising, as set out in Annex K2 to the application [lodged before the referring court] …, for the patient [identification] wristbands at issue [in the main proceedings] – in respect of which it is not disputed that they were supplied without anything printed thereon – produced by the US manufacturer Zebra Technologies Corp. [indicate] an intended purpose within the meaning of Article 2(12) of Regulation [2017/745]?

(2) In the event that the answer to question 1 is in the affirmative:

Are the patient [identification] wristbands at issue [in the main proceedings] – in respect of which it is not disputed that they were supplied without anything printed thereon – produced by the US manufacturer Zebra Technologies Corp. of the types "Direct Thermal Wristband Z-Band Ultrasoft" (Part. No. 10018856) and "LaserBand Advanced" – as depicted in Annex K1 to the application [lodged before the referring court] … – offered by the defendant [in the main proceedings] as "Patientenarmband ThermoComfort PLUS (Patient wristband ThermoComfort PLUS) (Article 511621)" and "Patientenarmband LaserBand A4 ungestanzt 'Erwachsene' mit Schutzfolie (Patient wristband LaserBand A4 unpunched 'Adult[s]' with protective foil) (Article 512099)" and advertised by the manufacturer Zebra Technologies Corp. …, medical devices within the meaning of Article 2(1) of Regulation [2017/745]?'

Consideration of the questions referred

20 By its two questions, which it is appropriate to examine together, the referring court asks, in essence, whether Article 2(1) of Regulation 2017/745 is to be interpreted as meaning that identification wristbands manufactured from a thermoplastic resin and intended to be worn by patients in the healthcare sector, which can be printed individually with letters, digits and/or a barcode in order to identify the person concerned and to save other data relating to him or her,

but which have been supplied completely blank, are to be classified as 'medical devices', within the meaning of that provision, and what role the 'intended purpose' of the device concerned, within the meaning of Article 2(12) of that regulation, plays in that regard.

21 Under Article 2(1) of Regulation 2017/745, a 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more specific medical purposes. Such purposes include, inter alia, the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, as well as the diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability. A medical device must not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but it may be assisted in its function by such means.

22 It follows that the intended purpose of a device, as formulated by its manufacturer, constitutes an important element of the definition of the concept of a 'medical device', even if it is not the only element of that definition. Indeed, Regulation 2017/745 does not define a medical device solely on the basis of how it is presented by its manufacturer, unlike in the case of medicinal products under Article 1(2)(a) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ 2001 L 311, p. 67).

23 Under Article 2(12) of Regulation 2017/745, the 'intended purpose' of a device means the use for which that device is intended according to the data supplied by its manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.

24 That definition is therefore based on two conditions. First, the data relating to the use for which the device concerned is intended must be supplied by the manufacturer of that device and, second, those data must be set out in one of the documents referred to in Article 2(12) of Regulation 2017/745.

25 In that regard, the file before the Court contains a document from the manufacturer of the patient identification wristbands at issue in the main proceedings, entitled 'High costs resulting from errors on wristbands', to which the applicant in the main proceedings refers, and according to which 'High-quality patient identification wristbands enable hospital staff to monitor the "five rights" at the patient's bedside: the right patient, the right medication, the right dose, the right time and the right route of administration. If errors occur in patient identification, they may have serious consequences.' That document also contains information on statistics regarding the frequency of causes of death, by which the manufacturer explains that medical errors are the third leading cause of death, after cardiovascular diseases and cancer. In addition, it specifies which medical errors are particularly frequent and refers, in that regard, to medication errors, errors in patient identification during procedures and tests, as well as errors in the allocation of blood products and in the labelling of patients' samples. According to that document, such errors result in annual costs of 17 billion to 29 billion United States dollars (USD) (approximately EUR 14.4 billion to EUR 24.6 billion).

26 Since the data supplied by Zebra as the manufacturer responsible for the patient identification wristbands at issue in the main proceedings are set out in that document, and since that document must be classified as promotional or sales material, the requisite conditions referred to in paragraph 24 of the present judgment have been satisfied. Consequently, those data contribute, in principle, to determining the intended purpose of the patient identification wristbands.

27 However, it must be stated that not all of those data are necessarily to be regarded as essential for determining the intended purpose of the products which they promote. It is apparent from the wording of Article 2(12) of Regulation 2017/745 that, in the definition of the concept of 'intended purpose' set out in that provision, the emphasis is placed on the use for which a device is intended according to the data supplied by the manufacturer of that device. Therefore, only the data that actually relate to the use of the product concerned are decisive.

28 In the context of classifying a product as a 'medical device', account must be taken not only of the data supplied by the manufacturer of the product, but also of whether or not that product objectively performs functions listed under Article 2(1) of Regulation 2017/745. In all the situations referred to in paragraph 25 of the present judgment, the patient identification wristbands at issue in the main proceedings are objectively not capable, by themselves, of providing a medical service, even though they are used in a medical context. In that regard, it should also be pointed out that, in the request for a preliminary ruling, the referring court notes that it is possible that some manufacturers may have affixed a CE marking under medical law and obtained the corresponding certification, as the case may be, simply for marketing purposes. It follows that it is true that the intended purpose of a device must be communicated by its manufacturer. However, the manufacturer's data must also be interpreted from the perspective of the recipient. In other words, while those data may be used to determine the intended purpose, they cannot, by themselves, necessarily determine that purpose.

29 It follows that contextual information which is merely useful in nature, contained in advertising and intended to promote the sale of certain products, is not decisive for determining the intended purpose of those products.

30 In the present case, although such contextual information may well be of some interest to the target public concerned, it does not provide any indication as to the medical use of the patient identification wristbands at issue in the main proceedings, since that information appears rather to encourage the relevant sectors to consider putting in place a patient identification system which functions reliably and which makes it possible to avoid or reduce the errors described in the document provided by Zebra, referred to in paragraph 25 of the present judgment. To that end, those identification wristbands are described only with regard to their use, namely patient identification.

31 Zentrale infers from that document that the patient identification wristbands at issue in the main proceedings are intended to enhance the reliability of medication, improve the reliability of tests and procedures, including operations and preventing errors in the identification of persons during operations, and to avoid errors during blood transfusions and sample collection, and thus, ultimately, to prevent deaths caused by medical errors. Zentrale therefore maintains that those identification wristbands contribute, within the meaning of Regulation 2017/745, to the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of diseases, injuries and disabilities. It adds that the four areas of application mentioned in that document,

namely ‘administration of medication’, ‘tests and procedures’, ‘blood transfusions’ and ‘sample collection’ also constitute, in themselves, intended purposes within the meaning of Article 2(12) of Regulation 2017/745.

32 However, contrary to what Zentrale claims, the intended purpose of the patient identification wristbands at issue in the main proceedings, as indicated by their manufacturer, is the correct identification of patients, since those identification wristbands are intended to ensure reliable access to the relevant data of patients throughout their stay, inter alia, in hospital. To that end, the identification wristbands in question may bear printed information such as the first name, surname, date of birth and file number of the patient concerned and, on an optional basis, the hospital department in which the person concerned is located.

33 However, it must be borne in mind that those identification wristbands were supplied unprinted. It follows that they are not intended to serve a specific medical purpose or to exert a physical action on the human body. Those identification wristbands do not serve any therapeutic, diagnostic or other specific medical purpose among those listed in Article 2(1) of Regulation 2017/745. Furthermore, they do not constitute products that are to be regarded as ‘medical devices’ within the meaning of the final two indents of that provision.

34 In addition, there is nothing in the file before the Court to indicate that the manufacturer of those identification wristbands had a clinical evaluation carried out, which also leads to the conclusion that those identification wristbands are not intended for medical purposes, within the meaning of that provision.

35 It must be stated, however, that the absence of a clinical evaluation does not preclude a product from being classified as a medical device.

36 In addition, it must be observed that, in the present case, the manufacturer, which also indicated that it operated in the printing sector and not in the medical devices sector, did not supply any medical data either on the label of the device concerned or in the instructions for use relating to that device. The only statements on which Zentrale relies, therefore, are the general commercial claims made by that manufacturer in the document referred to in paragraph 25 of the present judgment, according to which the use of high-quality patient identification wristbands enables healthcare staff to check whether it is the right patient, the right medication, the right dose, the right time and the right route of administration and, accordingly, enables them to reduce or avoid the negative consequences of errors relating to patient identification.

37 The correct identification of patients by healthcare staff therefore being the sole objective of the patient identification wristbands at issue in the main proceedings, it should be pointed out that all of the medical purposes referred to in Article 2(1) of Regulation 2017/745 depend, moreover, on other factors and not on whether or not the patient is wearing such an identification wristband.

38 In that context, it must be observed that that objective could also be achieved, for example, through the wearing of a nameplate, a personalised badge, a copy of an identity document or any other means of identification, which demonstrates that an identification wristband, as such, has no direct influence on diagnostic or therapeutic activities. It appears indisputable that the method of identifying a patient has no direct effect on the administration of medication, tests and procedures, blood transfusions or sample collection, as the patient identification wristbands at issue in the main proceedings perform a purely administrative function by facilitating the way in

which that patient can be identified by healthcare staff. It cannot therefore be claimed that those identification wristbands are used with other products for specific medical purposes, in accordance with Article 2(1) of Regulation 2017/745.

39 As regards, lastly, Zentrale's line of argument based on the judgment of 7 December 2017, *Snitem and Philips France* (C-329/16, EU:C:2017:947), that judgment was given in relation to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1).

40 According to Zentrale, in that judgment, the Court held that Article 1(1) and Article 1(2)(a) of Directive 93/42 must be interpreted as meaning that software, of which at least one of the functions makes it possible to use patient-specific data for the purposes, inter alia, of detecting contraindications, drug interactions and excessive doses, is, in respect of that function, a medical device within the meaning of those provisions, even if that software does not act directly in or on the human body.

41 In that regard, it must be stated that Zentrale's line of argument is based on a simplified reproduction of that judgment and that the approach adopted therein cannot be applied to the dispute in the main proceedings.

42 Indeed, it appears that the software at issue in the case which gave rise to the judgment of 7 December 2017, *Snitem and Philips France* (C-329/16, EU:C:2017:947), did not perform solely administrative functions like the patient identification wristbands at issue in the main proceedings; rather, that software, given that it processed the data which had been fed into it, also provided information to doctors with a view to assisting them in their work.

43 The Court observed that the wording of Article 1(2)(a) of Directive 93/42 had been amended by Article 2 of Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (OJ 2007 L 247, p. 21), recital 6 of which states that software is a medical device in its own right when specifically intended by its manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device; furthermore, that recital states that software for general purposes, when used in a healthcare setting, is not a medical device (judgment of 7 December 2017, *Snitem and Philips France*, C-329/16, EU:C:2017:947, paragraph 24).

44 The Court therefore held that the EU legislature made unequivocally clear that, in order for software to fall within the scope of Directive 93/42, it is not sufficient that it be used in a medical context; it is also necessary that the intended purpose, defined by the manufacturer, is specifically medical (judgment of 7 December 2017, *Snitem and Philips France*, C-329/16, EU:C:2017:947, paragraph 24).

45 Accordingly, the concept of a medical device cannot be regarded as including software that, while intended for use in a medical context, has the sole purpose of archiving, collecting and transmitting data, like patient medical data storage software, the function of which is limited to indicating to the doctor providing treatment the name of the generic drug associated with the one he or she plans to prescribe, or software intended to indicate the contraindications mentioned by the manufacturer of that drug in its instructions for use (judgment of 7 December 2017, *Snitem and Philips France*, C-329/16, EU:C:2017:947, paragraph 26).

46 It follows from all of the foregoing that the answer to the questions raised is that Article 2(1) and (12) of Regulation 2017/745 must be interpreted as meaning that patient identification wristbands manufactured from a thermoplastic resin and intended to be worn by patients in the healthcare sector, which, although they can be printed individually with letters, digits and/or a barcode in order to identify the patient concerned and to save other data relating to him or her, have been supplied completely blank, cannot be classified as 'medical devices' within the meaning of that provision.

Costs

47 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the referring court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Sixth Chamber) hereby rules:

Article 2(1) and (12) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC,

must be interpreted as meaning that patient identification wristbands manufactured from a thermoplastic resin and intended to be worn by patients in the healthcare sector, which, although they can be printed individually with letters, digits and/or a barcode in order to identify the patient concerned and to save other data relating to him or her, have been supplied completely blank, cannot be classified as 'medical devices' within the meaning of that provision.

[Signatures]