Council of the European Union

Brussels, 26 May 2025
(OR. en)

9327/25
ADD 1

Interinstitutional File:
2025/0133 (COD)

SIMPL 34	TELECOM 159
ANTICI 39	POLCOM 105
EF 167	COMPET 418
ECOFIN 593	ENV 395
MI 329	CLIMA 167
ECO 15	TRANS 202
ENT 78	ENER 159
IA 54	CODEC 677
IND 157	

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	21 May 2025
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2025) 503 annex
Subject:	ANNEXES to the Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications

Delegations will find attached document COM(2025) 503 annexes.

Encl.: COM(2025) 503 annex

EUROPEAN
COMMISSION

Brussels, 21.5.2025
COM(2025) 503 final

ANNEXES 1 to 13

ANNEXES

to the

Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Directives 2000/14/EC, 2011/65/EU, 2013/53/EU, 2014/29/EU, 2014/30/EU, 2014/31/EU, 2014/32/EU, 2014/33/EU, 2014/34/EU, 2014/35/EU, 2014/53/EU, 2014/68/EU and 2014/90/EU of the European Parliament and of the Council as regards digitalisation and common specifications

{SWD(2025) 130 final}

ANNEX I

Annexes II and V to VIII to Directive 2000/14/EC are amended as follows:

(1) Annex II is amended as follows:

(a) the first and second indents are replaced by the following:

‘— name, postal address and digital contact of the manufacturer or his authorised representative established in the Community

— name, postal address and digital contact of the person who keeps the technical documentation’;

(b) the fourth indent is replaced by the following:

‘— conformity assessment procedure followed, and, where appropriate, name, postal address and digital contact of the notified body involved’;

(2) Annex V is amended as follows:

(a) in point 2, the third sentence is replaced by the following:

‘In this case he has to include the name, postal address and digital contact of this person in the EC declaration of conformity.’;

(b) in point 3, the first indent is replaced by the following:

‘— name, postal address and digital contact of the manufacturer or his authorised representative established in the Community’;

(3) Annex VI is amended as follows:

(a) in point 2, the third sentence is replaced by the following:

‘In this case he has to include the name, postal address and digital contact of this person in the EC declaration of conformity.’;

(b) in point 3, the first indent is replaced by the following:

‘— name, postal address and digital contact of the manufacturer or his authorised representative established in the Community’;

(4) in Annex VII, point 2, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact in addition’;

(5) in Annex VIII, point 3.1, first indent, the first subindent is replaced by the following:

‘— name, postal address and digital contact of the manufacturer or his authorised representative established in the Community’.

ANNEX II

Annexes V and VI to Directive 2011/65/EU are amended as follows:

(1) in Annex V, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the applicant;’;

(2) Annex VI is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer or his authorised representative’;

(b) point 6 is replaced by the following:

‘6. Where applicable, references to the relevant harmonised standards or common specifications used or references to the technical specifications in relation to which conformity is declared:’.

ANNEX III

Annexes I, III, IV and V to Directive 2013/53/EU are amended as follows:

(1) Annex I is amended as follows:

(a) Part A is amended as follows:

(i) in point 2.1., the second subparagraph is replaced by the following:

‘Detailed requirements for the identification number referred to in the first paragraph are set out in the relevant harmonised standard or common specification.’;

(ii) in point 2.2, point (a) is replaced by the following:

‘(a) manufacturer’s name, registered trade name or registered trade mark and as well as the postal address and digital contact;’;

(b) Part B is amended as follows

(i) in point 1.1, point (a) is replaced by the following:

‘(a) engine manufacturer’s name, registered trade name or registered trade mark as well as the postal address and digital contact; and, if applicable, the name, postal address and digital contact of the person adapting the engine;’;

(ii) in point 2.3, the fourth subparagraph is replaced by the following:

‘Notified bodies may accept tests carried out on the basis of other tests cycles as specified in a harmonised standard or common specification and as applicable for the engine duty cycle.’;

(iii) in point 2.5, the second subparagraph is replaced by the following:

‘Notified bodies may accept tests carried out on the basis of other tests fuel as specified in a harmonised standard or common specification.’;

(iv) in point 4, point (b) is replaced by the following:

‘(b) specify the power of the engine when measured in accordance with the harmonised standard or common specification.’;

(2) Annex III is amended as follows:

(a) points (a), and (b) are replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer;

(b) the name, postal address and digital contact of the representative of the manufacturer established in the Union or, if appropriate, of the person responsible for the placing on the market;’;

(b) point (d) is replaced by the following:

‘(d) a statement that the partly completed watercraft complies with the essential requirements that apply at this stage of construction; this shall include references to the relevant harmonised standards or common specifications used, or references to the specifications in relation to which compliance is declared at this stage of construction; furthermore, it is intended to be completed by other legal or natural persons in full compliance with this Directive.’;

(3) Annex IV is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer or his authorised representative [The authorised representative must also give the business name, postal address and digital contact of the manufacturer] or the private importer.’;

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared:’;

(4) Annex V is amended as follows:

(a) in point 2, the first subparagraph is replaced by the following:

‘The person who is placing the product on the market or putting it into service shall lodge an application for a post-construction assessment of the product with a notified body and must provide the notified body, in electronic form, with the documents and technical file enabling the notified body to assess the conformity of the product with the requirements of this Directive and any available information on the use of the product after its first putting into service.’;

(b) in point 4.2, first subparagraph, the first sentence is replaced by the following:

‘The person who is placing the product on the market or putting it into service shall draw up, in electronic form, an EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the date the post-construction assessment certificate has been issued.’.

ANNEX IV

Annexes II, III and IV to Directive 2014/29/EU are amended as follows:

(1) Annex II is amended as follows:

(a) point 1.3 is amended as follows: :

(i) point (a) is replaced by the following

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(ii) in point (c), point (iv) is replaced by the following:

‘(iv) a list of the harmonised standards applied in full or in part, the references of which have been published in the *Official Journal of the European Union*, or common specifications, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(iii) in point (e), the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’;

(b) points 1.4.2., 1.4.3 and 1.4.4. are replaced by the following:

‘1.4.2. verify that the prototype vessel(s) has/have been manufactured in conformity with the technical documentation, that it may safely be used under its intended working conditions and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

1.4.3 carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;

1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of this Directive;’;

(c) in point 1.6, first paragraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;

(d) in point 3.3., first subparagraph, the second sentence is replaced by the following:

‘An adequate sample of the final vessels, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to check the conformity of the

vessel with the type described in the EU-type examination certificate and with the relevant requirements of this Directive.';

(2) in Annex III, point 1.2, point (e) is replaced by the following:

'(e) the name, registered trade name or registered trade mark as well as the postal address and digital contact of the manufacturer;';

(3) Annex IV is amended as follows

(a) point 2 is replaced by the following:

'2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative:';

(b) point 6 is replaced by the following:

'6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared:'.

ANNEX V

Annexes II, III and IV to Directive 2014/30/EU are amended as follows:

(1) in Annex II, point 3, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(2) Annex III, Part A is amended as follows:

(a) point 3 is amended as follows:

(i) point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(ii) in point (c), point (iv) is replaced by the following:

‘(iv) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, or common specifications, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(b) in point 6, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;

(3) Annex IV is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer or his authorised representative:’;

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used, including the date of the standard or common specification, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:’.

ANNEX VI

Annexes II and IV to Directive 2014/31/EU are amended as follows:

(1) Annex II is amended as follows:

(a) point 1.3 is amended as follows:

(i) point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(ii) in point (c), point (iv) is replaced by the following:

‘(iv) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(iii) in point (e), the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’;

(b) point 1.4.2, 1.4.3 and 1.4.4. are replaced by the following:

‘1.4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

1.4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;

1.4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Directive;’;

(c) in point 1.6, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;

(d) in point 2.3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(e) in point 2.3.3., the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(f) in point 3.2., point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, or common specifications, and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(g) in point 3.5.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(h) in point 3.5.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(i) point 4.4.1. is replaced by the following:

‘4.4.1. All instruments shall be individually examined and appropriate tests set out in the relevant harmonised standard(s), and/or in the relevant common specifications and/or other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’;

(j) in point 5.2.1., point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(k) point 5.5.1. is replaced by the following:

‘5.5.1. All instruments shall be individually examined and appropriate tests, set out in the relevant harmonised standards and/or equivalent tests set out in the relevant common specifications or other relevant technical specifications, shall be carried out to verify conformity with the requirements that apply to them. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.’;

(l) in point 6.2.1, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, or common specifications, and,

where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;';

(m) in point 6.4., the first subparagraph is replaced by the following:

'A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or in the relevant common specifications and/or other relevant technical specifications, to check the conformity of the instrument with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.';

(2) Annex IV is amended as follows:

(a) point 2 is replaced by the following:

'2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative';

(b) point 6 is replaced by the following:

'6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared:'.

ANNEX VII

Annexes II and XIII to Directive 2014/32/EU are amended as follows:

(1) Annex II is amended as follows:

(a) in Module A2: INTERNAL PRODUCTION CONTROL PLUS SUPERVISED INSTRUMENT CHECKS AT RANDOM INTERVALS, point 4, first subparagraph, the second and third sentences are replaced by the following:

'An adequate sample of the final measuring instruments, taken on site by the body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standard, and/or normative document, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify the conformity of the instruments with the relevant requirements of this Directive. In the absence of a relevant harmonised standard or normative document or common specification, the accredited in-house body or notified body concerned shall decide on the appropriate tests to be carried out.';

(b) Module B: EU-TYPE EXAMINATION is amended as follows:

(i) point 3 is amended as follows

– point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';

– point (e) is replaced by the following

'(e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards, and/or common specifications, and/or normative documents have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.';

(ii) in point 4, points 4.2, 4.3 and 4.4 are replaced by the following:

'4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or normative documents, and/or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, normative documents, and common specifications, these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards, and/or normative documents, and/or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of this Directive;';

(iii) in point 6, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;

(c) in Module C2: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED INSTRUMENT CHECKS AT RANDOM INTERVALS, point 3, first subparagraph, the second sentence is replaced by the following:

‘An adequate sample of the final measuring instrument, taken on site by the accredited in-house body or by the notified body before the placing on the market, shall be examined and appropriate tests, as identified by the relevant parts of the harmonised standards, and/or normative documents, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify the conformity of the instrument with the type described in the EU-type examination certificate and with the relevant requirements of this Directive.’;

(d) Module D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS is amended as follows:

(i) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(ii) in point 3.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(e) Module D1: QUALITY ASSURANCE OF THE PRODUCTION PROCESS, is amended as follows:

(i) in point 5.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(ii) in point 5.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(f) Module E: CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE is amended as follows:

(i) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well’;

(ii) in point 3.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(g) Module E1: QUALITY ASSURANCE OF FINAL INSTRUMENT INSPECTION AND TESTING is amended as follows:

(i) in point 5.1, point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well';

(ii) in point 5.3, the second subparagraph is replaced by the following:

'It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.';

(h) Module F: CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION, is amended as follows:

(i) in point 4, point 4.1 is replaced by the following:

'4.1. All measuring instruments shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or normative documents, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of a harmonised standard or normative document or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.';

(ii) in point 5, point 5.2 is replaced by the following:

'5.2. A random sample shall be taken from each lot according to the requirements of point 5.3. All measuring instruments in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or normative document(s), and/or common specification(s), and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the type described in the EU-type examination certificate and with the applicable requirements of this Directive, and to determine whether the lot is accepted or rejected. In the absence of such harmonised standard or normative document or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.';

(i) Module F1: CONFORMITY BASED ON PRODUCT VERIFICATION, is amended as follows:

(i) In point 5, point 5.1 is replaced by the following:

'5.1. All measuring instruments shall be individually examined and appropriate tests, set out in the relevant harmonised standards and/or normative documents, and/or common specifications and/or equivalent tests set out in other relevant technical specifications, shall be carried out to verify their conformity with the requirements that apply to them. In the absence of such a harmonised standard, or normative document, or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.';

(ii) in point 6, point 6.3 is replaced by the following:

'6.3. All measuring instruments in the sample shall be individually examined and appropriate tests set out in the relevant harmonised standards and/or normative documents, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify their conformity with the applicable requirements of this Directive and to determine whether the lot is accepted or rejected. In the absence of such harmonised standard, or normative document, or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.';

(j) in Module G: CONFORMITY BASED ON UNIT VERIFICATION, point 4, the first subparagraph is replaced by the following:

‘A notified body chosen by the manufacturer shall carry out the appropriate examinations and tests set out in the relevant harmonised standards, and/or normative documents, and/or common specifications or equivalent tests set out in other relevant technical specifications, to verify the conformity of the instrument with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard, or normative document, or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’;

(k) Module H: CONFORMITY BASED ON FULL QUALITY ASSURANCE, is amended as follows:

(i) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well’;

(ii) in point 3.2, point (b) is replaced by the following:

‘(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards, and/or normative documents, and/or common specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the measuring instruments will be met applying other relevant technical specifications;’;

(iii) in point 3.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(l) Module H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION is amended as follows:

(i) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well’;

(ii) in point 3.2., point (b) is replaced by the following:

‘(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards and/or normative documents, and/or common specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the measuring instruments will be met, applying other relevant technical specifications;’;

(iii) in point 3.3, first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(iv) point 4.2 is amended as follows:

– point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer’;

– point (d) is replaced by the following:

‘(d) the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or normative documents, and/or common specifications have not been applied in full, and shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications, by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.’;

(v) in point 4.3, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall give the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design.’;

(2) Annex XIII is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative’;

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or normative documents or common specifications used or references to the other technical specifications in relation to which conformity is declared:’.

ANNEX VIII

Annexes IIand VI to XII to Directive 2014/33/EU are amended as follows:

(1) Annex II is amended as follows:

(a) Part A is amended as follows:

(i) points (a) and (b) are replaced by the following:

‘(a) business name, postal address and digital contact of the manufacturer;

(b) where appropriate, business name, postal address and digital contact of the authorised representative;’;

(ii) point (h) are replaced by the following:

‘(h) where appropriate, reference(s) to harmonised standard(s) or common specification(s) used;’;

(iii) points (i) to (k) are replaced by the following:

‘(i) where appropriate, the name, postal address, digital contact and identification number of the notified body which carried out the EU-type examination of safety components for lifts set out in Annex IV, Part A and Annex VI, and the reference of the EU-type examination certificate issued by that notified body;

(j) where appropriate, the name, postal address, digital contact and identification number of the notified body which carried out the conformity to type with random checking for safety components for lifts set out in Annex IX;

(k) where appropriate, the name, postal address, digital contact and identification number of the notified body which approved the quality system operated by the manufacturer in accordance with the conformity assessment procedure set out in Annex VI or VII;’;

(b) Part B is amended as follows:

(i) points (a) and (b) are replaced by the following:

‘(a) business name, postal address and digital contact of the installer;

(b) where appropriate, business name, postal address and digital contact of the authorised representative;’;

(ii) points (g) is replaced by the following:

‘(g) where appropriate, reference(s) to harmonised standard(s) or common specifications used;’;

(iii) points (h) to (k) are replaced by the following:

(h) where appropriate, the name, postal address, digital contact and identification number of the notified body which carried out the EU-type examination of lifts set out in Annex IV, Part B and the reference of the EU-type examination certificate issued by that notified body;

(i) where appropriate, the name, postal address, digital contact and identification number of the notified body which carried out the unit verification for lifts set out in Annex VIII;

(j) where appropriate, the name, postal address, digital contact and identification number of the notified body which carried out the final inspection for lifts set out in Annex V;

(k) where appropriate, the name, postal address, digital contact and identification number of the notified body which approved the quality assurance system operated by the installer in accordance with the conformity assessment procedure set out in Annex X, XI or XII;’;

(2) Annex IV is amended as follows:

(a) Part A is amended as follows:

(i) in point 2, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well and the place of manufacture of the safety components for lifts;’;

(ii) in point 2(e), the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents, including other relevant technical specifications, that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’;

(iii) in point 3, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to enable the safety component for lifts to meet the conditions referred to in point 1, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(iv) in point 4, points (c), (d) and (e) are replaced by the following:

‘(c) verify that the representative specimen(s) has(have) been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

(d) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the specifications of the relevant harmonised standards or common specifications, these have been applied correctly;

(e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the specifications of the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications enable the safety component for lifts to meet the conditions referred to in point 1.’;

(v) in point 5, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the EU-type examination, any conditions of validity of the certificate and the particulars necessary to identify the approved type.’;

(b) Part B is amended as follows:

(i) in point 2, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the installer; and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(ii) in point 2(e), the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents, including other relevant technical specifications that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’;

(iii) in point 3, point (e) is replaced by the following:

‘(e) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of the Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;’;

(iv) in point 4, points (c), (d) and (e) are replaced by the following:

‘(c) examine the specimen lift to check that it has been manufactured in accordance with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

(d) carry out appropriate examinations and tests, or have them carried out, to check whether, where the installer has chosen to apply the specifications of the relevant harmonised standards or common specifications, these have been applied correctly;

(e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the specifications of the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the installer applying other relevant technical specifications meet the corresponding essential health and safety requirements of this Directive.’;

(v) in point 6, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the installer, the conclusions of the EU-type examination, any conditions of validity of the certificate and the particulars necessary to identify the approved type.’;

(3) Annex V is amended as follows:

(a) in point 2, point (b) is replaced by the following:

‘(b) a lift designed and manufactured in accordance with a quality system pursuant to Annex XI and the EU design examination certificate if the design is not wholly in accordance with the harmonised standards or common specifications.’;

(b) in point 3.1, the third subparagraph is replaced by the following:

‘The appropriate examinations and tests set out in the relevant harmonised standard(s) or common specifications, or equivalent tests shall be carried out in order to check the conformity of the lift with the applicable essential health and safety requirements set out in Annex I.’;

(c) in point 3.2, point (b) is replaced by the following:

‘(b) examination of the documents referred to in point 3.1 to check that the lift conforms with the lift designed and manufactured in accordance with an approved quality system pursuant to

Annex XI and if the design is not wholly in accordance with the harmonised standards or common specifications, with the EU design examination certificate.';

(4) Annex VI, is amended as follows:

(a) point 3.1, point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';

(b) in point 3.2., first subparagraph, the first sentence is replaced by the following:

'Under the quality system, each safety component for lifts shall be inspected and appropriate tests as set out in the relevant harmonised standards or common specifications, or equivalent tests shall be carried out in order to ensure that it meets the conditions referred to in point 1.';

(c) in point 3.3., first subparagraph, the second sentence is replaced by the following:

'It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard or common specifications.';

(5) Annex VII is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';

(b) in point 3.2, point (b) is replaced by the following:

'(b) the technical design specifications, including standards that will be applied and, where the relevant harmonised standards or common specifications will not be applied or not applied in full, the means, including other relevant technical specifications, that will be used to ensure that the conditions referred to in point 1 will be met;';

(c) in point 3.3, first subparagraph, the second sentence is replaced by the following:

'It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard or common specifications.';

(6) Annex VIII is amended as follows:

(a) in point 2.2, point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the installer, and if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';

(b) in point 3, point (e) is replaced by the following:

'(e) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of the Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;';

(c) in point 4, first subparagraph, the first sentence is replaced by the following:

‘The notified body chosen by the installer shall examine the technical documentation and the lift and carry out the appropriate tests as set out in the relevant harmonised standard(s) or common specification(s), or equivalent tests, to check its conformity with the applicable essential health and safety requirements set out in Annex I.’;

(7) Annex IX is amended as follows:

(a) in point 3, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’

(b) in point 4, first subparagraph, the second sentence is replaced by the following:

‘An adequate sample of the final safety components for lifts, taken on site by the notified body, shall be examined and appropriate tests set out in the relevant harmonised standards, and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, shall be carried out to check whether the safety components for lifts meets the conditions referred to in point 1.’;

(8) Annex X is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the installer, and if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(b) in point 3.2, the first subparagraph is replaced by the following:

‘Under the quality system, each lift shall be examined and appropriate tests as set out in the relevant harmonised standards or common specifications, or equivalent tests shall be carried out in order to ensure its conformity with the applicable essential health and safety requirements set out in Annex I.’;

(c) in point 3.3, first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard or common specifications.’;

(9) Annex XI is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the installer, and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;’;

(b) in point 3.2, point (b) is replaced by the following:

‘(b) the technical design specifications, including standards that will be applied and, where the relevant harmonised standards or common specifications will not be applied in full, the means, including other relevant technical specifications that will be used to ensure that the applicable essential health and safety requirements set out in Annex I will be met;’;

(c) in point 3.3, point 3.3.1 is replaced by the following:

‘3.3.1. When the design is not entirely in accordance with harmonised standards or common specifications, the notified body shall ascertain whether the design conforms to the essential health and safety requirements set out in Annex I and, if it does, issue an EU design

examination certificate to the installer, stating the limits of the certificate's validity and giving the details required for identification of the approved design.';

(d) in point 3.4, first subparagraph, the second sentence is replaced by the following:

'It shall presume conformity with those requirements in respect of the elements of the quality systems that comply with the corresponding specifications of the relevant harmonised standard or common specifications.';

(10) Annex XII is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the installer, and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;'

(b) in point 3.3, first subparagraph, the second sentence is replaced by the following:

'It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.'.

ANNEX IX

Annexes II to V and VII to X to Directive 2014/34/EU are amended as follows:

(1) in Annex II, point 1.0.5, the first indent is replaced by the following:

‘— name, registered trade name or registered trade mark as well as postal address and digital contact of the manufacturer,’;

(2) Annex III is amended as follows:

(a) in point 3, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’ ;

(b) in point 3, point (c), point (iv) is replaced by the following:

‘(iv) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union,* or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’

(c) in point 4, points 4.1, 4.2, and 4.3 are replaced by the following:

‘4.1. examine the technical documentation, verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications, as well as the elements which have been designed in accordance with other relevant technical specifications;

4.2. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications, these have been applied correctly;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential health and safety requirements of this Directive;’;

(d) in point 6, first subparagraph, the second sentence is replaced by the following:

‘That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;

(3) Annex IV is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(b) in point 3.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(4) in Annex V, point 4, point 4.1 is replaced by the following:

‘4.1. All products shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or common specification(s) and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’;

(5) Annex VII is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

‘(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(b) in point 3.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(6) in Annex VIII, point 2, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(7) Annex IX is amended as follows:

(a) in point 2.1, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* or common specifications and, where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(b) in point 4, the first subparagraph is replaced by the following:

‘A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or common specifications, and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the product with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out.’;

(8) Annex X is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative:’;

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared:’.

ANNEX X

Annexes III and IV to Directive 2014/35/EU are amended as follows:

(1) in Annex III, point 2, point (d) is replaced by the following:

‘(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union* or international or national standards referred to in Articles 13 and 14 or common specifications referred to in Article 12a and, where those harmonised standards or international or national standards or common specifications have not been applied, descriptions of the solutions adopted to meet the safety objectives of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or international or national standards referred to in Articles 13 and 14 or common specifications, the technical documentation shall specify the parts which have been applied;’;

(2) Annex IV is amended as follows:

(a) point 2 is replaced by the following:

‘2. Name, postal address and digital contact of the manufacturer or his authorised representative:’;

(b) point 6 is replaced by the following:

6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared:’.

ANNEX XI

Annexes Ia, and III to VII to Directive 2014/53/EU are amended as follows:

(1) in Annex Ia, Part II, the introductory sentence is replaced by the following:

'In the case of radio equipment falling within the scope of Article 3(4), first subparagraph, the following information shall be indicated in accordance with the requirements set out in Article 10(8):';

(2) Annex III, Module B: EU-type examination, is amended as follows:

(a) point 3 is amended as follows:

(i) point (a) and (d) are replaced by the following:

'(a) the name**,** postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;

(ii) in point (d), the second sentence is replaced by the following:

'That supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied or have not been fully applied. ';

(b) in point 6, first subparagraph, the second sentence is replaced by the following:

'That certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the aspects of the essential requirements covered by the examination, the conditions (if any) for its validity and the necessary data for identification of the assessed type.';

(c) in point 8, third subparagraph, the first sentence is replaced by the following:

'Each notified body shall inform the Member States of EU-type examination certificates it has issued and/or additions thereto in those cases where harmonised standards the references of which have been published in the Official Journal of the European Union or common specifications have not been applied or not been fully applied.';

(3) Annex IV is amended as follows:

(a) in point 3.1, point (a) is replaced by the following:

'(a) the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well;';

(b) in point 3.2, point (b) is replaced by the following:

'(b) the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards or common specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the radio equipment will be met;';

(c) in point 3.3, the second subparagraph is replaced by the following:

'It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.';

(4) in Annex V, point (d) is replaced by the following:

'(d) a list of the harmonised standards applied in full or in part the references of which have been published in the *Official Journal of the European Union*, or common specifications and,

where those harmonised standards or common specifications have not been applied, descriptions of the solutions adopted to meet the essential requirements set out in Article 3, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied;';

(5) Annex VI is amended as follows:

(a) point 2 is replaced by the following:

'2. Name, postal address and digital contact of the manufacturer or his authorised representative:';

(b) in point 6, the first sentence is replaced by the following:

'References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared.';

(6) Annex VII is deleted.

ANNEX XII

Annexes I, III and IV to Directive 2014/68/EU are amended as follows:

(1) Annex I is amended as follows:

(a) in point 3.1.2, the fifth subparagraph is replaced by the following:

'To carry out these approvals the third party must perform examinations and tests as set out in the appropriate harmonised standards or common specifications or equivalent examinations and tests or shall have them performed.';

(b) in point 4.2., point (b), the first indent is replaced by the following:

'— by using materials which comply with harmonised standards or common specifications,';

(c) in point 7, first subparagraph, the second sentence is replaced by the following:

'However, where they are not applied, including in cases where materials are not specifically referred to and no harmonised standards or common specifications are applied, the manufacturer shall demonstrate that appropriate measures have been taken to achieve an equivalent overall level of safety.';

(2) Annex III is amended as follows:

(a) in Part 1: Module A: (INTERNAL PRODUCTION CONTROL), point 2, the fourth indent is replaced by the following:

'— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and a description of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,';

(b) in Part 2: Module A2: INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS AT RANDOM INTERVALS, point 2, the fourth indent is replaced by the following:

'— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,';

(c) Part 3: Module B: EU-TYPE EXAMINATION is amended as follows:

(i) in point 3.1 EU-Type examination – production type, point 3 is amended as follows:

– in the second subparagraph, the first indent is replaced by the following:

'-the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,';

– in the second subparagraph, third indent, fourth subindent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

– in the fourth subparagraph, only indent, the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’;

(ii) in point 4.1, second subparagraph, the first indent is replaced by the following:

‘— assess the materials where these are not in conformity with the relevant harmonised standards or common specifications or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with point 4.3 of Annex I,’;

(iii) points 4.2., 4.3. and 4.4. are replaced by the following:

‘4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards or common specifications as well as the elements which have been designed using other relevant technical specifications without applying the relevant provisions of those standards.

4.3. carry out appropriate examinations and necessary tests to check whether when the manufacturer has chosen to apply the solutions the relevant harmonised standards or common specifications, these have been applied correctly.

4.4. carry out appropriate examinations and necessary tests to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements of this Directive.’;

(iv) in point 6, first subparagraph, the second sentence is replaced by the following:

‘Without prejudice to point 7, the certificate shall be valid for 10 years and be renewable and shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;

(v) in point 3.2. EU-Type examination – design type, point 3 is amended as follows:

– in the second subparagraph, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

– in the second subparagraph, third indent, the fourth subindent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

– in the second subparagraph, fourth indent, the second sentence is replaced by the following:

‘This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full.’;

(vi) in point 4.1., second subparagraph, the first indent is replaced by the following:

‘— assess the materials where these are not in conformity with the relevant harmonised standards or common specifications or with a European approval for pressure equipment materials,’;

(vii) points 4.2. and 4.3. are replaced by the following:

‘4.2. carry out appropriate examinations to check whether where the manufacturer has chosen to apply the solutions in the relevant harmonised standards or common specifications these have been applied correctly.

4.3. carry out appropriate examinations to check whether, where the solutions in the relevant harmonised standards or common specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential safety requirements of this Directive.’;

(viii) in point 6, first subparagraph, the second sentence is replaced by the following:

‘Without prejudice to point 7, the certificate shall be valid for 10 years and be renewable and shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved design.’;

(d) in Part 4: MODULE C2: CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRESSURE EQUIPMENT CHECKS AT RANDOM INTERVALS, point 3, the third subparagraph is replaced by the following:

‘An adequate sample of the final pressure equipment, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards, and/or common specifications, and/or equivalent tests applying other technical specifications, shall be carried out to check the conformity of the pressure equipment with the relevant requirements of this Directive.’;

(e) Part 5: MODULE D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS is amended as follows:

(i) in point 3.1, second subparagraph, the first indent is replaced by the following:

‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(ii) in point 3.3., the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(f) Part 6: MODULE D1: QUALITY ASSURANCE OF THE PRODUCTION PROCESS is amended as follows:

(i) in point 2, first subparagraph, the fourth indent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(ii) in point 5.1, second subparagraph, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(iii) in point 5.3, first subparagraph, the second sentence is replaced by the following:

‘The elements of the quality system which conform to the relevant harmonised standard or common specification are presumed to comply with the corresponding requirements referred to in point 5.2.’;

(g) Part 7: MODULE E: CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT QUALITY ASSURANCE is amended as follows:

(i) in point 3.1, second subparagraph, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(ii) in point 3.3, first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(h) Part 8: MODULE E1: QUALITY ASSURANCE OF FINAL PRESSURE EQUIPMENT INSPECTION AND TESTING is amended as follows:

(i) in point 2, first subparagraph, the fourth indent is replaced by the following:

‘— a list of the harmonised standards, the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(ii) in point 5.1, second subparagraph, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(iii) in point 5.3, the second subparagraph is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(i) in Part 9: MODULE F: CONFORMITY TO TYPE BASED ON PRESSURE EQUIPMENT VERIFICATION, point 4.1., the first subparagraph is replaced by the following:

‘All pressure equipment shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) or common specifications or equivalent tests shall be carried out in order to verify conformity with the approved type and described in the EU-type examination certificate and with the appropriate requirements of this Directive. In the absence of such a harmonised standard or common specification, the notified body concerned shall decide on the appropriate tests to be carried out.’;

(j) Part 10: MODULE G: CONFORMITY BASED ON UNIT VERIFICATION is amended as follows:

(i) in point 2, third subparagraph, the fourth indent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications, have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(ii) in point 4, the first subparagraph is replaced by the following:

‘A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standard(s), and/or common specifications, and/or equivalent tests, to check the conformity of the pressure equipment with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard or common specification the notified body concerned shall decide on the appropriate tests to be carried out applying other technical specifications.’;

(iii) in point 4, second subparagraph, the second indent is replaced by the following:

‘— assess the materials used where these are not in conformity with the relevant harmonised standards or common specifications or with a European approval for pressure equipment materials, and check the certificate issued by the material manufacturer in accordance with point 4.3 of Annex I,’;

(k) Part 11: MODULE H: CONFORMITY BASED ON FULL QUALITY ASSURANCE is amended as follows:

(i) point 3.1, second subparagraph, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(ii) in point 3.1, second subparagraph, second indent, the fourth subindent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(iii) in point 3.2, third subparagraph, the second indent is replaced by the following:

‘— the technical design specifications, including standards, that will be applied and, where the relevant harmonised standards or common specifications will not be applied in full, the means that will be used to ensure that the essential requirements of this Directive that apply to the pressure equipment will be met,’;

(iv) in point 3.3, first subparagraph, the second sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(l) Part 12: MODULE H1: CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION is amended as follows:

(i) in point 3.1, second subparagraph, the first indent is replaced by the following:

‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, his name, postal address and digital contact as well,’;

(ii) in point 3.1, second subparagraph, second indent, the fourth subindent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(iii) in point 3.2, third subparagraph, the second indent is replaced by the following:

‘— the technical design specifications, including standards, that will be applied and, where relevant harmonised standards or common specifications will not be applied in full, the means that will be used to ensure that the essential safety requirements of the Directive that apply to the pressure equipment will be met,’;

(iv) in point 3.3, second subparagraph, the first sentence is replaced by the following:

‘It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard or common specification.’;

(v) in point 4.2, the first indent is replaced by the following:

‘— the name, postal address and digital contact of the manufacturer,’;

(vi) in point 4.2, third indent, the fourth subindent is replaced by the following:

‘— a list of the harmonised standards the references of which have been published in the *Official Journal of the European Union*, or common specifications, applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements of this Directive, where those harmonised standards or common specifications have not been applied. In the event of partly applied harmonised standards or common specifications, the technical documentation shall specify the parts which have been applied,’;

(vii) in point 4.2, the fourth indent is replaced by the following:

‘— the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards or common specifications have not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer or by another testing laboratory on his behalf and under his responsibility.’;

(viii) in point 4.3, first subparagraph, the second sentence is replaced by the following:

‘The certificate shall give the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design.’;

(3) Annex IV is amended as follows:

(a) point 1 is replaced by the following:

‘1. Name, postal address and digital contact of the manufacturer and, where applicable, his authorised representative:’;

(b) point 6 is replaced by the following:

‘6. References to the relevant harmonised standards or common specifications used or references to the other technical specifications in relation to which conformity is declared:’;

(c) point 7 is replaced by the following:

‘7. Where appropriate, the name, postal address, digital contact and number of the notified body which carried out the conformity assessment and the number of the certificate issued, and a reference to the EU-type examination certificate – production type, EU-type examination certificate – design type, EU design examination certificate or certificate of conformity.’.

ANNEX XIII

Annex II to Directive 2014/90/EU is amended as follows:

(1) Part I: Module B: EC-TYPE EXAMINATION is amended as follows:

(a) in point 3, second subparagraph, the first indent is replaced by the following:

‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, its name, postal address and digital contact as well’;

(b) in point 6, first subparagraph, the second sentence is replaced by the following:

‘The certificate shall contain the name, postal address and digital contact of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type.’;

(2) in Part II: Module D: CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS, point 3.1, second subparagraph, the first indent is replaced by the following:

‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, its name, postal address and digital contact as well’;

(3) in Part III: Module E: CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE, point 3.1, second subparagraph, the first indent is replaced by the following:

‘- the name, postal address and digital contact of the manufacturer and, if the application is lodged by the authorised representative, its name, postal address and digital contact as well’.