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Guidance on standardisation for medical devices

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This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and a representative of the European Commission chairs it.

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Guidance on standardisation for medical devices

Introduction: scope and contents

This document aims to provide guidance on different aspects related to standards in the medical devices sector in support of the requirements laid down in the applicable EU legislation, taking into account its specificities.

The contents of this document:

are not intended to be exhaustive, and must be read and used within the legal and guidance framework on EU harmonisation legislation for health, safety and performance of products in the internal market, in particular for European standardisation.

Wider information on such legal and guidance framework is available from the references and sources of information indicated in the footnotes and at the end of this document.

1. EU legislation on medical devices within the "New Approach" and the "New Legislative Framework"

The **EU legislative framework on medical devices** consists of three current Directives[1] and two new Regulations[2]:

- **Directive 90/385/EEC on active implantable medical devices**[3] (AIMDD), applicable from 1 January 1993 until 25 May 2021;
- **Directive 93/42/EEC on medical devices**[4] (MDD), applicable from 1 January 1995 until 25 May 2021;
- **Directive 98/79/EC on *in vitro* diagnostic medical devices**[5] (IVDMDD), applicable from 7 June 2000 until 25 May 2022;
- **Regulation (EU) 2017/745 on medical devices**[6] (MDR), fully applicable from 26 May 2021;
- **Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices**[7] (IVDR), fully applicable from 26 May 2022.

These legislative acts are part of the EU harmonisation legislation on health, safety and performance of products in the internal market, based on the principles of the "**New Approach**" and the "**New Legislative Framework**"[8] policies. In this kind of legislation, the

[1] Current Directives: https://ec.europa.eu/health/md_sector/current_directives.

[2] New Regulations: https://ec.europa.eu/health/md_sector/new_regulations, https://ec.europa.eu/health/md_newregulations/overview.

[3] Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC) (OJ L 189, 20.7.1990, p. 17). Current consolidated version: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01990L0385-20071011.

[4] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1). Current consolidated version: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993L0042-20071011.

[5] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1). Current consolidated version: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01998L0079-20120111.

[6] 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 L 117 5.5.2017, p. 1). Current consolidated version: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20200424.

[7] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117 5.5.2017, p. 176). Current consolidated version: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0746-20170505.

[8] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30), and Decision No 768/2008/EC of the European

role of the **harmonised European standards** (hENs) is key: actually, for product characteristics, the content of legislation is limited to establishing essential requirements that products intended to be placed on the EU market must meet. The technical details and solutions supporting those essential requirements are laid down in harmonised European standards specifically developed by designated European standardisation organisations on the basis of specific standardisation requests (formerly known as "mandates") issued by the Commission.

Products designed and manufactured according to applicable harmonised European standards the references to which are published in the *Official Journal of the European Union* (OJEU) benefit from a **presumption of conformity** with the relevant legal requirements. In other words, the use of hENs cited in the OJEU confers presumption of conformity of the product with the legal requirements the standard aims to cover. This particular legal status of hENs cited in the OJEU generally allows manufacturers and the other sectorial actors (including notified bodies and national competent authorities) to make easier, quicker and less burdensome the processes related to conformity assessment procedures, affixing of the CE marking and placing on the market, market surveillance, etc.[9]. However, in general the use of harmonized standards is voluntary (see point 2.2.).

2. The general framework for harmonised European standards

2.1. Main references

The principles of the "New Approach" and the "New Legislative Framework" concerning standardisation are implemented through a specific **legal and guidance framework for European standardisation and harmonised European standards** in support of EU harmonisation legislation. The main references are:

- **Regulation (EU) No 1025/2012 on European standardisation**[10] ("the Standardisation Regulation"), directly applicable in all Member States from 1 January 2013. It lays down the legally binding provisions on European standardisation, among others on definitions (Article 2), standardisation organisations and bodies, standardisation requests (Article 10), formal objections (Article 11) and the Committee on Standards (Article 22);

Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

[9] For more details on the "New Approach" and the "New Legislative Framework" and its regulatory features, see "The 'Blue Guide' on the implementation of EU product rules": https://ec.europa.eu/docsroom/documents/18027/ and the Commission's website on CE marking: https://ec.europa.eu/growth/single-market/ce-marking/.

[10] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316 14.11.2012, p. 12). Current consolidated version: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02012R1025-20151007.

- **Rulings of the Court of Justice of the European Union** issued in specific cases[11] relevant for the whole EU standardisation system;

- **Vademecum on European standardisation**[12], compiling key documents and providing guidance on European standardisation policy and related practice, including standardisation requests, the role and use of harmonised standards, and other related resources;

- **Communication from the Commission** - Harmonised standards: Enhancing transparency and legal certainty for a fully functioning Single Market[13];

- **Action plan** - Structural solutions to decrease the stock of non-cited harmonised standards[14].

For the practical implementation of the abovementioned references, there is a set of specific documents, all of them in principle publicly available through the direct cooperation between the Commission and the European standardisation organisations:

- **Procedures and guidance for the CEN-Cenelec Management Centre** (CCMC)[15] and the their relevant Technical Committees developing standards (through the "Business Operation Support System"[16]);

- **Procedures and guidance for the HAS consultants** supporting the Commission ("Checklist - Verification of conditions for the publication of references of harmonised standards in the Official Journal", templates and instructions to fill in the assessment reports of harmonised standards, and other ad-hoc horizontal and sectorial guidance provided by the Commission). These guidance documents have also been made available by the Commission to the European standardisation organisations, with the invitation to circulate them among their Technical Committees.

2.2. Voluntary use of standards

As for the generality of the EU harmonisation legislation on products in the internal market based on the principles of the "New Approach" and the "New Legislative Framework" policies, the use of standards (either harmonised European standards cited in the *Official Journal of European Union* or any other standard) in the medical devices sector is and

[11] Among others: Case C-613/14 James Elliott Construction Limited v Irish Asphalt Limited; Case T-474/15 Global Garden Products Italy SpA (GGP Italy) v European Commission; Case C-630/16 Anstar Oy. See: https://curia.europa.eu/.

[12] https://ec.europa.eu/growth/single-market/european-standards/vademecum.

[13] COM(2018)764: https://ec.europa.eu/docsroom/documents/32615.

[14] https://ec.europa.eu/docsroom/documents/25881.

[15] https://www.cencenelec.eu/.

[16] https://boss.cen.eu/.

remains **voluntary**. This is clearly stated in the Standardisation Regulation (EU) 1025/2012 ruling the whole system:

- Recital (1): "*The primary objective of standardisation is the definition of voluntary technical or quality specifications with which current or future products, production processes or services may comply.*"

- Recital (2): "*European standardisation is organised by and for the stakeholders concerned based on national representation (the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec)) and direct participation (the European Telecommunications Standards Institute (ETSI)), and is founded on the principles recognised by the World Trade Organisation (WTO) in the field of standardisation, namely coherence, transparency, openness, consensus, voluntary application, independence from special interests and efficiency ('the founding principles').*"

- Article 2(1): "*'standard' means a technical specification, adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory, and which is one of the following: (a) 'international standard' means a standard adopted by an international standardisation body; (b) 'European standard' means a standard adopted by a European standardisation organisation; (c) 'harmonised standard' means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation; (d) 'national standard' means a standard adopted by a national standardisation body*".

These provisions are fully applicable also to the EU legislation on medical devices, which contains direct and indirect references to the voluntary use of standards, both in their recitals and enacting terms[17]. At the same time, it is worth noting that for medical devices there are "exceptions that proves the rule" when standards can be regarded as mandatory: it is the case of symbols and identification colours that "*shall conform to the harmonised standards*"[18] when harmonised standards containing indications on symbols or colour coding are available[19].

The voluntary character of the use of standards means in practice that the manufacturer may always choose to apply the technical solutions provided by harmonised European standards cited or not cited in the OJEU, or by non-harmonised European standards, or by any other

[17] Recitals and Articles 5(1) AIMDD, MDD and IVDMDD; Recitals and Articles 8(1) MDR and IVDR.

[18] MDD, Annex I, point 13.2.; IVDMDD, Annex I, point 8.2.; MDR, Annex I, point 23.1 h); IVDR, Annex I, point 20.1 h).

[19] For instance, the harmonised European standards EN ISO 15223-1:2016 *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)*, and EN ISO 5359:2008 *Low-pressure hose assemblies for use with medical gases (ISO 5359:2008)*+A1:2011.

international or national standards, or even to develop its own technical solutions, provided that it is able to demonstrate that these different or alternative non-harmonised means are adequate to comply with the legal requirements applicable to the product. Such a demonstration can be given by the manufacturer through a more in-depth risk assessment, gap analysis, etc., to be reflected in the related technical documents and reports within the prescribed conformity assessment procedures on the product.

Therefore, also in the medical devices field in the EU, **choosing to use a standard or not belongs to the manufacturer**, within its overall and ultimate responsibility on compliance. With the possible exceptions referred to above, it is not possible to impose the use of any specific standard, on the basis for instance of its status of harmonised European standard or of "state-of-the-art" standard, neither by national authorities in their market surveillance or vigilance activities, nor by notified bodies in the conformity assessment procedures they participate in. Actually, to be lawfully placed on the EU market, medical devices must comply with the health, safety and performance requirements of the applicable legislation, and not necessarily with the clauses of a standard. Conversely, compliance of a device must be assessed against the legal requirements that apply to it, and this may be made through compliance with the clauses of a standard (regardless of whether the standard is cited in the OJEU or not), but not necessarily, unless the manufacturer would claim compliance with the legal requirements by using a harmonised European standard cited in the OJEU thus conferring presumption of conformity.

2.3. The relationship between harmonised European standards and EU legislation: the "Annex Z"

The relationship between the clauses of a harmonised European standard drafted on the basis of a Commission's mandate or a standardisation request in support of specific EU legislation, and the requirements of such EU legislation that the standard aims to cover, is made explicit in the foreword of that standard and especially in a **separate informative annex, called "Annex Z"**. When a harmonised standard intends to cover more than one EU legislative act, it must include several Annexes Z (usually designated as "ZA", "ZB"… "ZZ"), each of them indicating the relevant legal requirements aimed to be covered by the normative contents of the standard.

The format of the Annex Z is determined by specific agreements between the Commission and the European standardisation organisations, to ensure that clear, precise and accurate information is provided to the users of harmonised European standards. It includes one or more tables listing the clauses of the standards, their correspondence with the legal requirements, and any other indications and comments necessary for the correct use of the standard (for instance, if some legal requirements are not covered or partially covered by the standard). In this sense, the role of Annexes Z is especially important for the purpose of legal clarity and certainty, being the necessary tool addressed to users of harmonised European standards to clearly **identify the contents of the standard that are appropriate to cover**

the requirements of the EU legislation and to confer the presumption of conformity with them, when the reference of the standard is cited in the OJEU. Annex Z also refers legal requirements not covered or partially covered, allowing the manufacturer to identify them and to implement additional action in order to comply with legal requirements. Without an adequate Annex Z, a harmonised standard lacks the necessary element of legal clarity and cannot be referenced in the OJEU, therefore its voluntary use cannot confer any presumption of conformity[20].

3. Harmonised European standards in support of the EU legislation on medical devices

3.1. Legal references, European standardisation organisations and standardisation mandates or requests

EU legislation on medical devices contain specific provisions on **harmonised standards** and the **presumption of conformity** conferred by its voluntary use when their references are published in the OJEU: they can be found in the Recitals and in the respective Articles 5(1) of the current Directives AIMDD, MDD and IVDMDD, and in the Recitals and the respective Articles 8(1) of the new Regulations MDR and IVDR. It is worth noting that the new Regulations define the term "harmonised standard" making reference to point (1)(c) of Article 2 of the Standardisation Regulation (EU) 1025/2012, as "*a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation*", while at the same time, the abovementioned Articles 8(1) specify that "*References in this Regulation to harmonised standards shall be understood as meaning harmonised standards the references of which have been published in the* Official Journal of the European Union", thus including the direct link to the presumption of conformity conferred by harmonised European standards cited in the OJEU[21].

Harmonised European standards in the field of healthcare engineering, including medical devices, are developed by the two relevant European standardisation organisations (ESOs): the **European Committee for Standardization (CEN)**[22] for most of the types of medical devices, and the **European Committee for Electrotechnical Standardization (Cenelec)**[23] especially for medical electrical equipment.

[20] It is important to remind that the requisite of having an Annex Z is not a new one for harmonised standards. In fact, CEN and Cenelec's Technical Boards formally decided in 1994 to introduce an informative Annex Z for harmonised standards, following extensive discussions with the Commission and with the Member States on how to ensure transparency on the correspondence between the clauses of harmonised standards and the legislative requirements covered.

[21] See for instance Case C-630/16 Anstar Oy.

[22] https://www.cen.eu/.

[23] https://www.cenelec.eu/.

According to Article 10 of the Standardisation Regulation (EU) 1025/2012, the Commission may request one or several European standardisation organisations to draft European standards or European standardisation deliverables according to specific requirements. This is the necessary legal basis for the development of harmonised European standards in support of the requirements of EU legislation, and to allow the publication in the OJEU of references to such standards to confer presumption of conformity. The essential legal relationship between harmonised standards and the standardisation requests (mandates) on which they are based has been confirmed by the jurisprudence of the Court of Justice of the European Union[24].

For the current Directives AIMDD, MDD and IVDMDD, such requests have the format of **standardisation mandates**, as letters addressed by the Commission to CEN and Cenelec. Several mandates have been issued between 1989 and 2010, some of them covering the whole scope of the Directives, and some others specific aspects only. The validity of those old standardisation mandates must necessarily expire in parallel to the Directives themselves.

For the new Regulations MDR and IVDR, a **standardisation request** has the improved format of a Commission Implementing Decision (pursuant to the entry into force of the Standardisation Regulation), structured in recitals (reasons, objectives and contents of the act), articles (requested activities, requirements and timelines) and annexes (lists of existing standards to be revised and of new standards to be developed under the MDR and the IVDR, and specific requirements). Before adopting the standardisation request, the Commission must seek the opinion of the Committee set up by Article 22 of the Standardisation Regulation (EU) 1025/2012.

Once adopted in the three working languages of European standardisation (English, French and German), the "*Commission Implementing Decision on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council*" is published in the Commission's database on standardisation mandates[25] and addressed to CEN and Cenelec. When accepted, it becomes applicable for the development of harmonised European standards in the field of medical devices and, later on, for the publication in the OJEU of their references to confer presumption of conformity with the legal requirements the standards aim to cover.

The MDR/IVDR Standardisation Request is intended to be regularly revised and updated when deemed necessary, in particular with respect to the lists of standards in the Annexes, to ensure its continuous adaptation to the evolution of the standardisation work at European and international level, as well as innovation in the field of medical devices.

[24] See footnote 11.

[25] https://ec.europa.eu/growth/tools-databases/mandates/.

3.2. Development of harmonised European standards for medical devices and assessment by the HAS consultants

On the basis of the relevant standardisation mandates or requests, **CEN and Cenelec develop harmonised European standards** in the field of medical devices through their specific Technical Committees (TCs). The process include several phases, following the internal rules of the European standardisation organisations, aimed to ensure the highest quality of the standards produced, with the adequate participation of national and international experts, stakeholders and interested parties[26].

During the standardisation process, specific assessment of the draft standards under development is carried out by the "**Harmonised Standards (HAS) consultants**", as technical experts supporting the Commission services, to ensure the compliance of the draft harmonised standards with the relevant EU legislative framework and with the relevant standardisation request (mandate). This assessment of draft harmonised standards is an obligation that the Commission, together with the European Standardisation organisations, has pursuant to Article 10(5) of the Standardisation Regulation, and the HAS consultants complement the Commission's expertise and resources needed for this task. Their activities are based on the rules on European standardisation and on specific procedures, guidance documents and templates, to carry out the necessary technical and legal assessments and to provide reports to the Commission at three specific phases of the standardisation development process (the so-called milestones: First Committee Draft, Enquiry and Formal Vote). As such, the HAS consultants work under the instructions of the Commission and must keep their full independence from the European standardisation organisations and their TCs. The smooth management, coordination and follow up of such activities include periodical initiatives by the Commission for exchange of information and feedback at horizontal and vertical level (training sessions, webinars, alignment and sectorial meetings, etc.) to guarantee a common approach and the effectiveness of the work.

In the field of "Healthcare Engineering", there are currently four HAS consultants for standards in support of the EU legislation on medical devices, administratively managed by an external entity according to a specific contract stipulated with the Commission[27].

3.3. Publication in the OJEU of references to harmonised European standards to confer presumption of conformity

Once CEN and Cenelec complete their standardisation work by publishing new or revised harmonised European standards in the field of medical devices, they propose to the

[26] More information on the development of European standards is available on the websites of the European standardisation organisations, CEN: https://www.cen.eu/ and Cenelec: https://www.cenelec.eu/, and their Management Centre: https://www.cencenelec.eu/.

[27] More information: https://assets.ey.com/content/dam/ey-sites/ey-com/en_be/topics/advisory/ey-has-call-for-expression-of-interest.pdf.

Commission the **publication of the references to such standards in the OJEU**, to make them conferring the presumption of conformity with the legal requirements the standards aim to cover. The Commission carry out the final assessment on compliance of these proposed standards with the requirements of the legislation as well as of the relevant standardisation mandate or request, taking into account the assessment reports by the HAS consultants (which are however not binding for the Commission), to decide to publish, not to publish or publish with restrictions the references in the OJEU. In case of not publication or publication with restrictions, the Commission inform the European standardisation organisations accordingly.

Since December 2018, the publications in the OJEU of lists of references to harmonised European standards in support of the current Directives on medical devices must have the format of **Commission Implementing Decisions**[28] in the "L" series. These acts with an improved and more robust legal format replace the previous publications as Commission Communications in the "C" series and are structured in recitals, articles and annexes that contain the lists of references: those to standards conferring presumption of conformity (both already published and those published for the first time, usually presented as a consolidate list) and those to standards withdrawn for being superseded by new standards, or for becoming obsolete.

The change of publication system was announced by the Commission in its Communication on harmonised standards of 22.11.2018[29] and is a logical consequence of the jurisprudence of the Court of Justice of the European Union[30].

3.4. International aspects of standardisation

In the medical devices sector, most of the European standards are developed by CEN and Cenelec in parallel to international standardisation developed by the **International Organization for Standardization (ISO)**[31] and the **International Electrotechnical Commission (IEC)**[32], on the basis of the Vienna Agreement (1991) and the Dresden Agreement (1996) reconfirmed by the Frankfurt Agreement (2016) respectively[33]. Within such agreements, the normative texts of the respective standards are substantially the same, while harmonised European standards must also contain a "European foreword" and the Annex(es) Z necessary to link the clauses of the standard with the requirements of the EU legislation(s) the standard aims to cover. This is especially important to clearly identify in each standard which clauses are suitable to confer presumption of conformity with the legal

[28] Latest publication under the current Directives on medical devices: OJ L 090I, 25.3.2020, pp. 1, 25 and 33.

[29] COM(2018)764: https://ec.europa.eu/docsroom/documents/32615.

[30] In particular, the ruling in Case C-613/14 James Elliott Construction Limited v Irish Asphalt Limited.

[31] https://www.iso.org/.

[32] https://www.iec.ch/.

[33] CEN-Cenelec international cooperation: https://www.cencenelec.eu/intcoop/.

requirements and those not, in view of the publication in the OJEU of the reference of that standard. It is the responsibility of CEN and Cenelec to prepare and add the European foreword and the Annex(es) Z to the ISO/IEC standards when they adopt them as EN ISO or EN IEC standards intended to be harmonised in support of EU legislation on medical devices.

On the other hand, the **International Medical Device Regulators Forum (IMDRF)** is a voluntary group of medical device regulators from around the world (the management committee is currently integrated by Australia, Brazil, Canada, China, European Union, Japan, Russia, Singapore, South Korea and United States of America), to promote international and regional regulatory harmonisation, convergence and recognition in the field of medical devices, by providing guidance on strategies, polices and operational directions. The specific IMDRF Standards Working Group developed different initiatives and documents, such as "*IMDRF recognised standards*"[34], "*Standards - Improving the quality of international medical device standards for regulatory use*"[35], "*Optimizing standards for regulatory use*"[36] and "GHTF/SG1/N044:2008 *Role of Standards in the Assessment of Medical Devices*"[37] of the Global Harmonisation Task Force (GHTF).

3.5. The concept of "state of the art", European standardisation and conformity assessment for medical devices

As in other harmonised sectors, the EU legislation on medical devices – both the current Directives and the new Regulations – contains a number of references to the need to "***take into account the generally acknowledged state of the art***"[38] to comply with the health, safety and performance requirements. However, it is important to underline that "taking into account" is different from "compliance", due to the fact that "state of the art" is not a legally defined concept and it involves several and complex aspects, difficult to be expressed in a single and clear definition. Actually, there are different sources providing **references, definitions and practical examples on the "state of the art"**, all of them non-legally binding but still useful to consider. It is the case of horizontal and vertical guidance documents, agreements of working parties, European and international standards, sectorial papers etc., as the following ones, among others:

- "*The concept of essential requirements is based on the assumption that the harmonised standards reflect generally acknowledgeable state of the art and the ESO review*

[34] http://www.imdrf.org/workitems/wi-imdrfstandards.asp.

[35] http://www.imdrf.org/workitems/wi-standards.asp.

[36] http://www.imdrf.org/consultations/cons-swg-optimising-standards-n51-180524.asp.

[37] http://www.imdrf.org/docs/ghtf/final/sg1/procedural-docs/ghtf-sg1-n044-2008-standards-in-assessment-of-medical-devices-080305.pdf.

[38] Among others, in particular in the AMDD, MDD and IVDMDD in their respective Annexes I "Essential requirements", and in the MDR and IVDR in their respective Annexes I "General safety and performance requirements".

standards regularly" ("The 'Blue Guide' on the implementation of EU product rules"[39], section 4.1.2.5., p. 49).

- "*The most recent editions of standards published by the standardisers should be considered as reflecting state-of-the-art, regardless of the OJ referencing*" (COM statement, Minutes of the meeting of the MDCG Subgroup on Standards held on 20 May 2019[40], item 3, p. 1).

- "*The current knowledge/ state of the art in the corresponding medical field, such as applicable standards and guidance documents, information relating to the medical condition managed with the device and its natural course, benchmark devices, other devices and medical alternatives available to the target population*" (MEDDEV 2.7/1 revision 4 - Clinical evaluation: a guide for manufacturers and notified bodies under Directives 93/42/EEC and 90/385/EEC[41], section 7., p. 16).

- "*State of the Art: Developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience. NOTE 1: The state of the art embodies what is currently and generally accepted as good practice in technology and medicine. The state of the art does not necessarily imply the most technologically advanced solution. The state of the art described here is sometimes referred to as the 'generally acknowledged state of the art'. (Modified from ISO/IEC Guide 2:2004)*" (IMDRF/GRRP WG/N47 FINAL:2018 Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices[42], 3.43, p. 11).

- "*'State of the art': IMDRF/GRRP WG/N47 provides the following definition: Developed stage of current technical capability and/or accepted clinical practice in regard to products, processes and patient management, based on the relevant consolidated findings of science, technology and experience. Note: The state-of-the-art embodies what is currently and generally accepted as good practice in technology and medicine. The state-of-the-art does not necessarily imply the most technologically advanced solution. The state-of-the-art described here is sometimes referred to as the 'generally acknowledged state-of-the-art'*" (MDCG 2020-6 - Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC. A guide for manufacturers and notified bodies[43], section 1.2., pp. 5-6).

[39] https://ec.europa.eu/docsroom/documents/18027/.

[40] https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupMeetingDoc&docid=35082.

[41] https://ec.europa.eu/docsroom/documents/17522/attachments/1/translations/.

[42] http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf.

[43] https://ec.europa.eu/docsroom/documents/40904.

- "*State of the art: developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience. Note: The state of the art embodies what is currently and generally accepted as good practice in technology and medicine. The state of the art does not necessarily imply the most technologically advanced solution. The state of the art described here is sometimes referred to as the 'generally acknowledged state of the art' [Source: ISO/IEC Guide 63:2019, 3.18]*" (EN ISO 14971:2019 *Medical devices - Application of risk management to medical devices (ISO 14971:2019)*[44], section 3.28, p. 6).

In order to have a clear reference especially with respect to the practical implementation of the concept, it is commonly considered that **the most recent versions of standards with the technical solutions they contain reflect the "state of the art"**. However, due to the non-legal status of the concept of "state of the art" and its complexity, with so many different and dynamic aspects to be taken into account, **the mere compliance with the most recent version of a standard which reference is not listed in the OJEU does not automatically imply compliance with the requirements of the applicable EU legislation**, if no further evidences are provided in the technical documentation of the product. Actually, "state-of-the-art" standards do not confer any presumption of conformity if their references are not cited in the OJEU, as harmonised European standards developed by the ESOs on the basis of a standardisation mandate or request issued by the Commission.

Therefore, recalling that in the EU harmonisation legislation for health and safety of products in the internal market – including also medical devices legislation – the use of standards is and remains voluntary (with the exceptions referred to in point 2.2. above), **it is not possible to impose the use of a specific standard in the conformity assessment of a product**, not even on the basis of "compliance with the state of the art": the "state of the art" expressed by standards must be taken into account but it does not mean "compliance" that must be granted with respect to the legal requirements and not to standards. In particular, for conformity assessment procedures requiring its intervention, the notified body must check whether the concerned device complies with the requirements of the Directives or Regulations on medical devices, but cannot make any standard "mandatory": choosing to use a standard or not, as appropriate and applicable, belongs to the manufacturer, within its overall and ultimate responsibility on the legal compliance of products intended to be placed on the EU market.

44 https://standards.cen.eu/dyn/www/f?p=204:110:0::::FSP_PROJECT,FSP_ORG_ID:63920,581003&cs=17914C9013F1D49765AA9CD9E135F8AC9.

4. Governance structure for standards in the medical devices sector

4.1. The MDCG Subgroup on Standards

Within the governance structure of the **Medical Device Coordination Group (MDCG)** established by Article 103 of Regulation (EU) 2017/745 and its 13 specific subgroups, the **MDCG Subgroup on Standards (Working Group 2)** is devoted to standardisation issues. It aims to provide technical expertise for the positions of the MDCG and opinions of the Committee on Standards related to the sector, including standardisation requests, publication of references in the *Official Journal of the European Union*, formal objections to harmonised standards, and so on.

The MDCG Subgroup on Standards is chaired by the Commission and integrated by the national competent authorities of the EU Member States (as members) and of other countries where the EU legislation is applicable, as well as by stakeholders' organisations fulfilling certain criteria (as observers) after selection via public calls for applications. The list of members and observers, the key documents for its operation (Rules of Procedure, Terms of Reference, calls for applications) and the documents related to its meetings and other activities (Agendas, Minutes, others) are publicly available in the specific space of the "**Medical Device Coordination Group (X03565)**" in the "Register of Commission expert groups and other similar entities"[45].

The activities of the MDCG Subgroup on Standards are supported by two **CIRCABC interest groups**, for circulation of information and exchange of documents: the "MDCG - Standards (CAs)"[46] for EU national competent authorities as members, and the "MDCG - Standards (Stks)"[47] for stakeholders' organisations as observers.

4.2. The CEN-Cenelec Advisory Board on Healthcare Standards (ABHS)

The **Advisory Board on Healthcare Standards (ABHS)** is the CEN and Cenelec sector forum for medical devices, established in 2005 to bring together European stakeholders interested in or impacted by standardisation in the healthcare field. It is integrated by experts in medical devices standardisation, mainly from national standardisation organisations, Technical Committees, European federations and societal stakeholders; the European Commission participates as observer. The ABHS usually meets once or twice per year, to present and discuss relevant issues related to standardisation in support of EU legislation on medical devices, cooperation with the European Commission and with the international standardisation organisations, agreements on common positions and guidance documents or "white papers", etc.

[45] https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3565.

[46] https://circabc.europa.eu/ui/group/40ffa918-04f6-442e-b278-12e596c5e06a.

[47] https://circabc.europa.eu/ui/group/b47c1365-18cf-4015-9bf1-f6a146c72f32.

References and sources of information

Both **horizontal and vertical/sectorial references** are listed here, mainly from the Commission but also from other relevant actors for standardisation in the medical devices field.

- EUR-Lex - Access to European Union law: https://eur-lex.europa.eu/
  - *Official Journal of the European Union* (OJEU): https://eur-lex.europa.eu/oj/direct-access.html
- Court of Justice of the European Union: https://curia.europa.eu/
- Medical devices sector - Overview: https://ec.europa.eu/health/md_sector/overview
  - Current Directives: https://ec.europa.eu/health/md_sector/current_directives
  - New Regulations: https://ec.europa.eu/health/md_sector/new_regulations
  - Guidance documents: https://ec.europa.eu/health/md_sector/new_regulations/guidance
  - Market surveillance and vigilance: https://ec.europa.eu/health/md_sector/market-surveillance-and-vigilance
  - Contacts: https://ec.europa.eu/health/md_sector/contact
  - Latest updates: https://ec.europa.eu/health/md-sector/latest_updates
- Medical devices - New Regulations - Overview: https://ec.europa.eu/health/md_newregulations/overview
  - Getting ready: https://ec.europa.eu/health/md_newregulations/getting_ready
  - Guidance: https://ec.europa.eu/health/md_newregulations/guidance
  - Publications and factsheets: https://ec.europa.eu/health/md_newregulations/publications
- Medical devices - Topics of interest - Overview, Harmonised European standards: https://ec.europa.eu/health/md_topics-interest/overview
  - Notified bodies: https://ec.europa.eu/health/md_topics-interest/notified_bodies
- Medical devices - Dialogue between interested parties - Overview: https://ec.europa.eu/health/md_dialogue/overview
  - MDCG Working Groups: https://ec.europa.eu/health/md_dialogue/mdcg_working_groups
  - International cooperation: https://ec.europa.eu/health/md_dialogue/international_cooperation
- Medical Device Coordination Group (X03565) in the "Register of Commission expert groups and other similar entities": https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3565

- Medical device - Docsroom: https://ec.europa.eu/docsroom/documents?locale=en&keywords=medical%20device

- CIRCABC (Communication and Information Resource Centre for Administrations, Businesses and Citizens): https://circabc.europa.eu/
  - MDCG - Standards (CAs): https://circabc.europa.eu/ui/group/40ffa918-04f6-442e-b278-12e596c5e06a
  - MDCG - Standards (Stks): https://circabc.europa.eu/ui/group/b47c1365-18cf-4015-9bf1-f6a146c72f32

- The 'Blue Guide' on the implementation of EU product rules: https://ec.europa.eu/docsroom/documents/18027/

- CE marking: https://ec.europa.eu/growth/single-market/ce-marking/

- Technical documentation and EU declaration of conformity: https://europa.eu/youreurope/business/product-requirements/compliance/technical-documentation-conformity/

- Single market for goods: https://ec.europa.eu/growth/single-market/goods
  - New legislative framework: https://ec.europa.eu/growth/single-market/goods/new-legislative-framework
  - Market surveillance for products: https://ec.europa.eu/growth/single-market/goods/building-blocks/market-surveillance

- European standards: https://ec.europa.eu/growth/single-market/european-standards
  - Standardisation policy: https://ec.europa.eu/growth/single-market/european-standards/policy
  - Harmonised standards: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards
    - Standardisation - Notification system: https://ec.europa.eu/growth/single-market/european-standards/notification-system
    - Standardisation mandates and requests: https://ec.europa.eu/growth/tools-databases/mandates/
    - References to harmonised European standards published in the *Official Journal of the European Union* (OJEU) in support of:
      - Directive 90/385/EEC: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/implantable-medical-devices
      - Directive 93/42/EEC [and Regulation (EU) 2017/745]: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices
      - Directive 98/79/EC [and Regulation (EU) 2017/746]: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices

- Notified bodies: https://ec.europa.eu/growth/single-market/goods/building-blocks/notified-bodies
  - NANDO (New Approach Notified and Designated Organisations) information system: https://ec.europa.eu/growth/tools-databases/nando/
    - for Directive 90/385/EEC: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=8
    - for Directive 93/42/EEC: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=13
    - for Directive 98/79/EC: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=20
    - for Regulation (EU) 2017/745: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=34
    - for Regulation (EU) 2017/746: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=35

- European standardisation organisations (ESOs):
  - European Committee for Standardization (CEN): https://www.cen.eu/
    - Business Operations Support System: https://boss.cen.eu/
    - Medical equipment, pharmaceuticals and personal care products: https://www.cen.eu/work/Sectors/Healthcare/Pages/Medicalequipment.aspx
  - European Committee for Electrotechnical Standardization (Cenelec): https://www.cenelec.eu/
  - CEN-Cenelec Management Centre (CCMC): https://www.cencenelec.eu/
    - Medical devices: https://www.cencenelec.eu/standards/Sectorsold/healthcare/MedicalDevices/Pages/default.aspx
    - International cooperation: https://www.cencenelec.eu/intcoop/

- International standardisation organisations:
  - International Organization for Standardization (ISO): https://www.iso.org/
  - International Electrotechnical Commission (IEC): https://www.iec.ch/

- International Medical Device Regulators Forum (IMDRF): http://www.imdrf.org/

EUROPEAN
COMMISSION

M/575

Brussels, 14.4.2021
C(2021) 2406 final

COMMISSION IMPLEMENTING DECISION

of 14.4.2021

on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council

(Only the English, French and German texts are authentic)

COMMISSION IMPLEMENTING DECISION

of 14.4.2021

on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council

(Only the English, French and German texts are authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council[1], and in particular Article 10(1) thereof,

Whereas:

(1) Regulation (EU) 2017/745 of the European Parliament and of the Council[2] lays down safety and performance requirements for medical devices for human use and system and process requirements for economic operators and sponsors of clinical investigations, in order to ensure a high level of protection of health and safety for patients and users and the smooth functioning of the internal market. Regulation (EU) 2017/746 of the European Parliament and of the Council[3] lays down such requirements for in vitro diagnostic medical devices for human use.

(2) In accordance with Article 8(1) of Regulation (EU) 2017/745 and Article 8(1) of Regulation (EU) 2017/746, devices and economic operators or sponsors that are in conformity with the relevant harmonised standards or the relevant parts thereof, the references of which have been published in the Official Journal of the European Union, are to be presumed to be in conformity with the requirements of Regulations (EU) 2017/745 or (EU) 2017/746 covered by those standards or parts thereof.

(3) Harmonised standards help ensuring a high level of protection of the health and safety for patients and users throughout the Union and thus contribute to the free movement of devices in the Union. Given that such standards are technology-neutral and

[1] OJ L 316, 14.11.2012, p. 12.

[2] 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 L 117, 5.5.2017, p. 1).

[3] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

performance-based, they also contribute to ensuring equal conditions of competition among economic operators dealing with devices, in particular small and medium-sized enterprises that are active in this sector. Indirectly, those standards also contribute to lower sales costs, benefitting patients and users in particular.

(4) Regulation (EU) 2017/745 replacing Council Directive 90/385/EEC[4] and Council Directive 93/42/EEC[5], and Regulation (EU) 2017/746 replacing Directive 98/79/EC of the European Parliament and of the Council[6] modify, among others, the requirements regarding design and manufacture of devices, labelling and instructions for use of such devices, and clinical investigation and performance studies concerning such devices. Those Regulations also modify the rules on the quality management system and set out detailed principles for the risk management requiring reduction of risks as far as possible without adversely affecting the benefit-risk ratio.

(5) Several harmonised standards have been drafted in support of Directives 90/385/EEC, 93/42/EEC and 98/79/EC on the basis of standardisation mandates issued by the Commission. Those harmonised standards need to be revised to take into account the requirements set out in Regulations (EU) 2017/745 and (EU) 2017/746.

(6) Standards developed at international level by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) on the basis of the Vienna agreement[7] and the Frankfurt agreement[8] need to be adopted as harmonised standards by the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) after adapting them to the Union legal framework.

(7) It is also necessary to draft new harmonised standards in relation to the requirements set out in Regulations (EU) 2017/745 and (EU) 2017/746.

(8) The intention to request a review or an update of the existing harmonised standards and drafting of new harmonised standards in support of Regulations (EU) 2017/745 and (EU) 2017/746 is stated in point 18 of the Commission Staff Working Document on the implementation of the actions foreseen in the annual Union work programme for European standardisation for 2018[9] accompanying that programme[10].

(9) CEN and Cenelec have indicated that the work covered by the request falls within their area of competence.

(10) It is therefore appropriate to request CEN and Cenelec to revise the existing harmonised standards and to draft new harmonised standards in support of Regulations (EU) 2017/745 and (EU) 2017/746.

(11) The harmonised standards should include detailed technical specifications in relation to the requirements set out in Regulations (EU) 2017/745 and (EU) 2017/746, especially with respect to the design and manufacture of devices, risk management and the obligations on economic operators and sponsors, including those relating to quality

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4 Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

5 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

6 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

7 Agreement on technical co-operation between ISO and CEN (Version 3.3 of 20 September 2001).

8 IEC-CENELEC Agreement on common planning of new work and parallel voting (Edition 3 of October 2016).

9 SWD(2017) 284 final of 25 August 2017.

10 COM(2017) 453 final of 25 August 2017.

management systems, risk management, clinical investigations and performance studies, and clinical evaluation and clinical evidence. They should also indicate clearly the correspondence between the technical specifications and the requirements they aim to cover.

(12) In accordance with point 1 of Chapter I of Annex I to Regulation (EU) 2017/745 and point 1 of Chapter I of Annex I to Regulation (EU) 2017/746, devices are to be safe and effective and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. Technical specifications included in the harmonised standards should support the attainment of those objectives.

(13) In accordance with point (h) of section 23.1 of Chapter III of Annex I to Regulation (EU) 2017/745 and point (h) of section 20.1 of Chapter III of Annex I to Regulation (EU) 2017/746, the information supplied by the manufacturer of the device is to take the form of internationally recognised symbols conforming to the harmonised standards or common specifications. Moreover, in accordance with Article 10(11) of Regulation (EU) 2017/745 and Article 10(10) of Regulation (EU) 2017/746, the use of symbols in device information is to take into account the intended users or patients. In order to ensure that users, patients and economic operators understand correctly the meaning of any such symbols, a description of the meaning of the symbols should be publicly available, without prejudice to any copyright to the relevant harmonised standard or its parts.

(14) Information as to which legal requirements are covered or partially covered by a harmonised standard is necessary when assessing, in accordance with Article 10(5) of Regulation (EU) No 1025/2012, the compliance of the documents drafted by CEN and Cenelec. Such information is also necessary before publication of references of harmonised standards in the Official Journal of the European Union in accordance with Article 10(6) of Regulation (EU) No 1025/2012. In each harmonised standard, CEN and Cenelec should therefore specify the extent to which the technical specifications included in the harmonised standard aim to cover one or several requirements set out in Regulation (EU) 2017/745 or Regulation (EU) 2017/746.

(15) The European standardisation organisations have agreed to follow the Guidelines for the execution of standardisation requests[11].

(16) In order to ensure transparency and facilitate the execution of the requested standardisation activities, CEN and Cenelec should prepare a work programme and submit it to the Commission.

(17) In order to enable the Commission to better monitor the requested standardisation work, CEN and Cenelec should provide the Commission with access to an overall project plan containing detailed information on the execution of the standardisation request and should report regularly on the execution of that request.

(18) Experience shows that during execution of the standardisation request, it may be necessary to adjust the scope of the request or the deadlines set therein. CEN and Cenelec should therefore promptly report to the Commission if they consider that more time is required to draft the standards than initially foreseen or that it is

[11] SWD(2015) 205 final of 27 October 2015.

appropriate to adapt the scope of the request in order to allow the Commission to take appropriate action.

(19) In accordance with Article 10(3) of Regulation (EU) No 1025/2012, each standardisation request is subject to acceptance by the relevant European standardisation organisation. It is therefore necessary to provide for rules on the validity of this request if it is not accepted by CEN or Cenelec.

(20) In order to ensure legal certainty as to the validity of the request after its execution, it is appropriate to provide for a date of expiry of this Decision.

(21) Given that Directives 90/385/EEC and 93/42/EEC are repealed as of 26 May 2021 and Directive 98/79/EC is repealed as of 26 May 2022, it is appropriate to provide for the end of validity of standardisation mandates that have been issued by the Commission for drafting harmonised standards in support of those Directives.

(22) Given that a standardisation request as regards medical devices in support of Regulations (EU) 2017/745 and (EU) 2017/746 set out in Implementing Decision C(2020) 2532[12] was not accepted by CEN and Cenelec, it is appropriate to repeal that Decision.

(23) The European standardisation organisations, the European stakeholders' organisations receiving Union financing, and the Medical Device Coordination Group established by Article 103 of Regulation (EU) 2017/745 have been consulted.

(24) Article 5(1) of Implementing Decision C(2020) 2532 contains an error by providing for expiry of standardisation mandate 'M/321 of 13 June 2002' on 26 May 2020. Mandate 'M/321 of 13 June 2002' is also referred to in Article 5(2) of Implementing Decision C(2020) 2532 providing for its expiry on 26 May 2022, which is the correct expiry date.

(25) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 22 of Regulation (EU) No 1025/2012,

HAS ADOPTED THIS DECISION:

Article 1

Requested standardisation activities

1. The European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are requested to revise the existing harmonised standards listed in Table 1 of Annex I to this Decision and to draft the new harmonised standards listed in Table 2 of that Annex in support of Regulation (EU) 2017/745 for medical devices by the deadlines set in that Annex.

2. CEN and Cenelec are requested to revise the existing standards listed in Table 1 of Annex II to this Decision and to draft the new harmonised standards listed in Table 2 of that Annex in support of Regulation (EU) 2017/746 for *in vitro* diagnostic medical devices by the deadlines set in that Annex.

3. The standards referred to in paragraphs 1 and 2 shall meet the requirements set out in Annex III.

[12] Commission Implementing Decision C(2020) 2532 of 15 May 2020 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council.

4. CEN and Cenelec shall provide the Commission with the titles of the requested standards in all official languages of the Union.

Article 2

Work programme

1. CEN and Cenelec shall prepare a joint work programme indicating all the standards listed in Annexes I and II, the responsible technical bodies and a timetable for the execution of the requested standardisation activities in line with the deadlines set out in those Annexes.

2. CEN and Cenelec shall submit the joint work programme to the Commission by 28 May 2021. CEN and Cenelec shall inform the Commission of any amendments to the joint work programme.

3. CEN and Cenelec shall provide the Commission with access to an overall project plan.

Article 3

Reporting

1. CEN and Cenelec shall report annually to the Commission on the execution of the standardisation request referred to in Article 1, indicating the progress made in implementation of the work programme referred to in Article 2.

2. CEN and Cenelec shall submit the first joint annual report to the Commission by 16 April 2022. Subsequent joint annual reports shall be submitted to the Commission by 31 October each year.

3. CEN and Cenelec shall provide the Commission with the joint final report by 30 June 2024.

4. CEN and Cenelec shall promptly report to the Commission any major concerns relating to the scope of the standardisation request referred to in Article 1 or the deadlines set in Annexes I and II.

Article 4

Validity of the standardisation request

If CEN or Cenelec do not accept the standardisation request referred to in Article 1 within a month of receiving it, the request may not constitute a basis for the standardisation activities referred to in that Article.

This Decision shall expire on 31 December 2024.

Article 5

Expiry of existing standardisation mandates and repeal of Implementing Decision C(2020) 2532

1. The following standardisation mandates shall expire on 26 May 2022:

   (a) M/252 of 12 September 1997;

   (b) M/321 of 13 June 2002;

   (c) M/384 of 6 April 2006.

2. Implementing Decision C(2020) 2532 is repealed.

Article 6

Addressees

This Decision is addressed to the European Committee for Standardization and the European Committee for Electrotechnical Standardization.

Done at Brussels, 14.4.2021

For the Commission
Stella KYRIAKIDES
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION

EUROPEAN
COMMISSION

Brussels, 14.4.2021
C(2021) 2406 final

ANNEXES 1 to 3

ANNEXES

to the

COMMISSION IMPLEMENTING DECISION

on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council

ANNEX I

List of existing standards to be revised and list of new standards to be drafted as referred to in Article 1(1)

Table 1: List of existing harmonised standards to be revised and deadlines for the adoption of the revised harmonised standards

Reference information		Deadline for the adoption
1.	EN 285:2015 Sterilization - Steam sterilizers - Large sterilizers	27 May 2024
2.	EN 455-1:2020 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes	27 May 2024
3.	EN 455-2:2015 Medical gloves for single use - Part 2: Requirements and testing for physical properties	27 May 2024
4.	EN 455-3:2015 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation	27 May 2024
5.	EN 455-4:2009 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	27 May 2024
6.	EN 556-1:2001+AC:2006 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	27 May 2024
7.	EN 556-2:2015 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices	27 May 2024
8.	EN 1422:2014 Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods	27 May 2024

9.	EN 1865-1:2010+A1:2015 Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment	27 May 2024
10.	EN 1865-2:2010+A1:2015 Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher	27 May 2024
11.	EN 1865-3:2012+A1:2015 Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher	27 May 2024
12.	EN 1865-4:2012 Patient handling equipment used in road ambulances - Part 4: Foldable patient transfer chair	27 May 2024
13.	EN 1985:1998 Walking aids - General requirements and test methods	27 May 2024
14.	EN ISO 4074:2015 Natural rubber latex male condoms - Requirements and test methods	27 May 2024
15.	EN ISO 5359:2014+A1:2017 Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases	27 May 2024
16.	EN ISO 5840-1:2015 Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements	27 May 2024
17.	EN ISO 5840-2:2015 Cardiovascular implants - Cardiac valve prostheses - Part 2: Surgically implanted heart valve substitutes	27 May 2024
18.	EN ISO 5840-3:2013 Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques	27 May 2024
19.	EN ISO 7010:2020+A1:2020	27 May 2024

	Graphical symbols - Safety colours and safety signs - Registered safety signs	
20.	EN ISO 7197:2009 Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components	27 May 2024
21.	EN ISO 7396-1:2016+A1:2019 Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum	27 May 2024
22.	EN ISO 7396-2:2007 Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems	27 May 2024
23.	EN ISO 9713:2009 Neurosurgical implants - Self-closing intracranial aneurysm clips	27 May 2024
24.	EN ISO 10328:2016 Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods	27 May 2024
25.	EN ISO 10524-1:2019 Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices	27 May 2024
26.	EN ISO 10524-2:2019 Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators	27 May 2024
27.	EN ISO 10524-3:2019 Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves (VIPRs)	27 May 2024
28.	EN ISO 10535:2006 Hoists for the transfer of disabled persons - Requirements and test methods	27 May 2024
29.	EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1:	27 May 2024

	Evaluation and testing within a risk management process	
30.	EN ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	27 May 2024
31.	EN ISO 10993-4:2017 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	27 May 2024
32.	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity	27 May 2024
33.	EN ISO 10993-6:2016 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	27 May 2024
34.	EN ISO 10993-7:2008+AC:2009 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	27 May 2024
35.	EN ISO 10993-9:2009 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	27 May 2024
36.	EN ISO 10993-10:2013 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	27 May 2024
37.	EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	27 May 2024
38.	EN ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	27 May 2024
39.	EN ISO 10993-13:2010 Biological evaluation of medical devices - Part 13:	27 May 2024

	Identification and quantification of degradation products from polymeric medical devices	
40.	EN ISO 10993-14:2009 Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	27 May 2024
41.	EN ISO 10993-15:2009 Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	27 May 2024
42.	EN ISO 10993-16:2017 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	27 May 2024
43.	EN ISO 10993-17:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	27 May 2024
44.	EN ISO 10993-18:2020 Biological evaluation of medical devices - Part 18: Chemical characterization of materials	27 May 2024
45.	EN ISO 11135:2014+A1:2019 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	27 May 2024
46.	EN ISO 11137-1:2015+A2:2019 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	27 May 2024
47.	EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	27 May 2024

48.	EN ISO 11140-1:2014 Sterilization of health care products - Chemical indicators - Part 1: General requirements	27 May 2024
49.	EN ISO 11140-3:2009 Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test	27 May 2024
50.	EN ISO 11140-4:2007 Sterilization of health care products - Chemical indicators - Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration	27 May 2024
51.	EN ISO 11197:2019 Medical supply units	27 May 2024
52.	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	27 May 2024
53.	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	27 May 2024
54.	EN ISO 11737-1:2018 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products	27 May 2024
55.	EN ISO 11737-2:2020 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	27 May 2024
56.	EN ISO 11810:2015 Lasers and laser-related equipment - Test method and classification for the laser resistance of surgical drapes and/or patient protective covers - Primary ignition,	27 May 2024

	penetration, flame spread and secondary ignition	
57.	EN ISO 11990:2018 Lasers and laser-related equipment - Determination of laser resistance of tracheal tube shaft and tracheal cuffs	27 May 2024
58.	EN 12183:2014 Manual wheelchairs - Requirements and test methods	27 May 2024
59.	EN 12184:2014 Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods	27 May 2024
60.	EN ISO 12417-1:2015 Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products - Part 1: General requirements	27 May 2024
61.	EN ISO 12870:2018 Ophthalmic optics - Spectacle frames - Requirements and test methods	27 May 2024
62.	EN 13060:2014+A1:2018 Small steam sterilizers	27 May 2024
63.	EN ISO 13408-1:2015 Aseptic processing of health care products - Part 1: General requirements	27 May 2024
64.	EN ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Filtration	27 May 2024
65.	EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization	27 May 2024
66.	EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies	27 May 2024
67.	EN ISO 13408-5:2011	27 May 2024

	Aseptic processing of health care products - Part 5: Sterilization in place	
68.	EN ISO 13408-6:2011+A1:2013 Aseptic processing of health care products - Part 6: Isolator systems	27 May 2024
69.	EN ISO 13408-7:2015 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products	27 May 2024
70.	EN ISO 13485:2016+AC:2018 Medical devices - Quality management systems - Requirements for regulatory purposes	27 May 2024
71.	EN 13718-1:2014+A1:2020 Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances	27 May 2024
72.	EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns	27 May 2024
73.	EN 13795-2:2019 Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits	27 May 2024
74.	EN 13976-1:2018 Rescue systems - Transportation of incubators - Part 1: Interface requirements	27 May 2024
75.	EN 13976-2:2018 Rescue systems - Transportation of incubators - Part 2: System requirements	27 May 2024
76.	EN 14139:2010 Ophthalmic optics - Specifications for ready-to-wear spectacles	27 May 2024
77.	EN ISO 14155:2020 Clinical investigation of medical devices for human	27 May 2024

	subjects - Good clinical practice	
78.	EN ISO 14160:2011 Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	27 May 2024
79.	EN 14180:2014 Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing	27 May 2024
80.	EN ISO 14602:2011 Non-active surgical implants - Implants for osteosynthesis - Particular requirements	27 May 2024
81.	EN ISO 14607:2018 Non-active surgical implants - Mammary implants - Particular requirements	27 May 2024
82.	EN ISO 14630:2012 Non-active surgical implants - General requirements	27 May 2024
83.	EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods	27 May 2024
84.	EN 14885:2018 Chemical disinfectants and antiseptics - Application of European standards for chemical disinfectants and antiseptics	27 May 2024
85.	EN ISO 14889:2013+A1:2017 Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses	27 May 2024
86.	EN ISO 14937:2009 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	27 May 2024

87.	EN ISO 14971:2019 Medical devices - Application of risk management to medical devices	27 May 2024
88.	EN ISO 15001:2011 Anaesthetic and respiratory equipment - Compatibility with oxygen	27 May 2024
89.	EN ISO 15004-1:2020 Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments	27 May 2024
90.	EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	27 May 2024
91.	EN ISO 15883-1:2009+A1:2014 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests	27 May 2024
92.	EN ISO 15883-2:2009 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.	27 May 2024
93.	EN ISO 15883-3:2009 Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	27 May 2024
94.	EN ISO 15883-4:2018 Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes	27 May 2024
95.	EN ISO 15883-6:2015 Washer-disinfectors - Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment	27 May 2024

96.	EN ISO 15883-7:2016 Washer-disinfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment	27 May 2024
97.	EN ISO 16061:2015 Instrumentation for use in association with non-active surgical implants - General requirements	27 May 2024
98.	EN ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices	27 May 2024
99.	EN ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	27 May 2024
100.	EN ISO 18562-1:2020 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process	27 May 2024
101.	EN ISO 18562-2:2020 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter	27 May 2024
102.	EN ISO 18562-3:2020 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs)	27 May 2024
103.	EN ISO 18562-4:2020 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate	27 May 2024
104.	EN ISO 20857:2013 Sterilization of health care products - Dry heat -	27 May 2024

	Requirements for the development, validation and routine control of a sterilization process for medical devices	
105.	EN ISO 21534:2009 Non-active surgical implants - Joint replacement implants - Particular requirements	27 May 2024
106.	EN ISO 21535:2009+A1:2016 Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants	27 May 2024
107.	EN ISO 21536:2009+A1:2014 Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants	27 May 2024
108.	EN ISO 21987:2017 Ophthalmic optics - Mounted spectacle lenses	27 May 2024
109.	EN ISO 22442-1:2020 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management	27 May 2024
110.	EN ISO 22442-2:2020 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling	27 May 2024
111.	EN ISO 22442-3:2007 Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents	27 May 2024
112.	EN ISO 22523:2006 External limb prostheses and external orthoses - Requirements and test methods	27 May 2024
113.	EN ISO 22675:2016 Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods	27 May 2024

114.	EN ISO 23908:2013 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling	27 May 2024
115.	EN ISO 25424:2019 Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices	27 May 2024
116.	EN ISO 25539-1:2017 Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses	27 May 2024
117.	EN ISO 25539-2:2020 Cardiovascular implants - Endovascular devices - Part 2: Vascular stents	27 May 2024
118.	EN ISO 25539-3:2011 Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters	27 May 2024
119.	EN 50637:2017 Medical electrical equipment - Particular requirements for the basic safety and essential performance of medical beds for children	27 May 2024
120.	EN 60118-0:2015 Electroacoustics - Hearing aids - Part 0: Measurement of the performance characteristics of hearing aids	27 May 2024
121.	EN IEC 60118-13:2020 Electroacoustics - Hearing aids - Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices	27 May 2024
122.	EN 60601-1:2006+A1:2013+AC:2014+A12:2014 +A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential	27 May 2024

	performance	
123.	EN 60601-1-2:2015+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	27 May 2024
124.	EN 60601-1-3:2008+AC:2014+A11:2016+A1:2020 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment	27 May 2024
125.	EN 60601-1-6:2010+A1:2015+A2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	27 May 2024
126.	EN 60601-1-8:2007+AC:2014+A11:2017+A2:2020 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	27 May 2024
127.	EN 60601-1-10:2008+A1:2015+A2:2020 Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral standard: Requirements for the development of physiologic closed-loop controller	27 May 2024
128.	EN 60601-1-11:2015+A1:2020 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	27 May 2024
129.	EN 60601-1-12:2015+A1:2020 Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical	27 May 2024

	systems intended for use in the emergency medical services environment	
130.	EN 60601-2-1:2015 Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV	27 May 2024
131.	EN IEC 60601-2-2:2018 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	27 May 2024
132.	EN 60601-2-3:2015+A1:2016 Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment	27 May 2024
133.	EN 60601-2-4:2011+A1:2019 Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators	27 May 2024
134.	EN 60601-2-5:2015 Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment	27 May 2024
135.	EN 60601-2-6:2015+A1:2016 Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment	27 May 2024
136.	EN 60601-2-8:2015+A1:2016 Medical electrical equipment - Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV	27 May 2024
137.	EN 60601-2-10:2015+A1:2016 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential	27 May 2024

	performance of nerve and muscle stimulators	
138.	EN 60601-2-11:2015 Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment	27 May 2024
139.	EN IEC 60601-2-16:2019 Medical electrical equipment - Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment	27 May 2024
140.	EN 60601-2-17:2015 Medical electrical equipment - Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment	27 May 2024
141.	EN 60601-2-18:2015 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	27 May 2024
142.	EN IEC 60601-2-19:2020 Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators	27 May 2024
143.	EN IEC 60601-2-20:2020 Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators	27 May 2024
144.	EN IEC 60601-2-21:2020 Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	27 May 2024
145.	EN 60601-2-23:2015 Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure	27 May 2024

	monitoring equipment	
146.	EN 60601-2-24:2015 Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers	27 May 2024
147.	EN 60601-2-25:2015 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	27 May 2024
148.	EN 60601-2-27:2014 Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	27 May 2024
149.	EN IEC 60601-2-28:2019 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	27 May 2024
150.	EN 60601-2-29:2008+A11:2011 Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators	27 May 2024
151.	EN IEC 60601-2-31:2020 Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source	27 May 2024
152.	EN 60601-2-33:2010+A11:2011+A1:2015+A2:2015+A12:2016 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	27 May 2024
153.	EN 60601-2-34:2014 Medical electrical equipment - Part 2-34: Particular	27 May 2024

	requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment	
154.	EN 60601-2-36:2015 Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy	27 May 2024
155.	EN 60601-2-37:2008+A11:2011+A1:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	27 May 2024
156.	EN IEC 60601-2-39:2019 Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment	27 May 2024
157.	EN 60601-2-40:2019 Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment	27 May 2024
158.	EN 60601-2-41:2009+A11:2011+A1:2015 Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis	27 May 2024
159.	EN 60601-2-43:2010+AC:2014+A1:2018+A2:2020 Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures	27 May 2024
160.	EN 60601-2-44:2009+A11:2011+A1:2012+A2:2016 Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	27 May 2024

161.	EN 60601-2-45:2011+A1:2015 Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices	27 May 2024
162.	EN IEC 60601-2-46:2019 Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables	27 May 2024
163.	EN 60601-2-47:2015 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	27 May 2024
164.	EN 60601-2-50:2009+A11:2011+A1:2016 Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	27 May 2024
165.	EN 60601-2-52:2010+AC:2011+A1:2015 Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds	27 May 2024
166.	EN 60601-2-54:2009+A1:2015+A2:2019 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	27 May 2024
167.	EN 60601-2-62:2015 Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment	27 May 2024
168.	EN 60601-2-63:2015+A1:2019 Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment	27 May 2024

169.	EN 60601-2-64:2015 Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment	27 May 2024
170.	EN 60601-2-65:2013+A1:2020 Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment	27 May 2024
171.	EN IEC 60601-2-66:2020 Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems	27 May 2024
172.	EN 60601-2-68:2015 Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment	27 May 2024
173.	EN IEC 60601-2-75:2019 Medical electrical equipment - Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment	27 May 2024
174.	EN IEC 60601-2-76:2019 Medical electrical equipment - Part 2-76: Particular requirements for the basic safety and essential performance of low energy ionized gas haemostasis equipment	27 May 2024
175.	EN IEC 60601-2-83:2020 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment	27 May 2024
176.	EN 61010-1:2010+A1:2019+AC:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1:	27 May 2024

	General requirements	
177.	EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	27 May 2024
178.	EN 62083:2009 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems	27 May 2024
179.	EN 62304:2006+A1:2015 Medical device software - Software life-cycle processes	27 May 2024
180.	EN 62366-1:2015+AC:2015+AC:2016+A1:2020 Medical devices - Application of usability engineering to medical devices	27 May 2024
181.	EN 80001-1:2011 Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software - Part 1: Application of risk management	27 May 2024
182.	EN ISO 80369-1:2018 Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements	27 May 2024
183.	EN ISO 80369-3:2016 Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications	27 May 2024
184.	EN ISO 80369-5:2016+AC:2017-02 Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications	27 May 2024
185.	EN ISO 80369-6:2016 Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications	27 May 2014

186.	EN ISO 80369-7:2017 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications	27 May 2024
187.	EN ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	27 May 2024
188.	EN ISO 80601-2-12:2020 Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators	27 May 2024
189.	EN ISO 80601-2-13:2011+A1:2019+A2:2019 Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation	27 May 2024
190.	EN IEC 80601-2-26:2020 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs	27 May 2024
191.	EN IEC 80601-2-30:2019 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	27 May 2024
192.	EN IEC 80601-2-35:2019 Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use	27 May 2024
193.	EN IEC 80601-2-49:2019 Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment	27 May 2024

194.	EN ISO 80601-2-56:2017+A1:2020 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	27 May 2024
195.	EN 80601-2-58:2015+A1:2019 Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery	27 May 2024
196.	EN IEC 80601-2-59:2019 Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening	27 May 2024
197.	EN IEC 80601-2-60:2020 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment	27 May 2024
198.	EN ISO 80601-2-69:2020 Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment	27 May 2024
199.	EN IEC 80601-2-71:2018 Medical electrical equipment - Part 2-71: Particular requirements for the basic safety and essential performance of functional near-infrared spectroscopy (NIRS) equipment	27 May 2024
200.	EN IEC 80601-2-78:2020 Medical electrical equipment - Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation	27 May 2024
201.	EN 82304-1:2017 Health Software - Part 1: General requirements for product safety	27 May 2024

Table 2: List of new harmonised standards to be drafted and deadlines for their adoption

Reference information		Deadline for the adoption
1.	Medical gloves for single use - Part 5: Extractable chemical residues (prEN 455-5)	27 May 2024
2.	Radiation protection - Sealed radioactive sources - Leakage test methods (ISO 9978)	27 May 2024
3.	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23)	27 May 2024
4.	Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices (ISO 14117)	27 May 2024
5.	Stainless steel steam boilers (prEN 14222)	27 May 2024
6.	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer (ISO 14708-1)	27 May 2024
7.	Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers (ISO 14708-2)	27 May 2024
8.	Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators (ISO 14708-3)	27 May 2024
9.	Implants for surgery - Active implantable medical devices - Part 4: Implantable infusion pumps (ISO 14708-4)	27 May 2024
10.	Implants for surgery - Active implantable medical devices - Part 5: Circulatory support devices (ISO 14708-5)	27 May 2024
11.	Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) (ISO 14708-6)	27 May 2024
12.	Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear	27 May 2024

	and auditory brainstem implant systems (ISO 14708-7)	
13.	Washer-disinfectors - Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy (ISO 15883-5)	27 May 2024
14.	Sterilizers for medical purposes - Low temperature vapourized hydrogen peroxide sterilizers - Requirements and testing (prEN 17180)	27 May 2024
15.	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664-1)	27 May 2024
16.	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Medical devices not intended for direct patient contact (ISO 17664-2)	27 May 2024
17.	Assistive products for personal hygiene that support users - Requirements and test methods (ISO 17966)	27 May 2024
18.	Medical devices - Connectors for reservoir delivery systems for healthcare applications (ISO 18250)	27 May 2024
19.	Medical devices - Information to be provided by the manufacturer (ISO 20417)	27 May 2024
20.	Assistive products - General requirements and test methods (ISO 21856)	27 May 2024
21.	Lasers and laser-related equipment - Test methods for laser-induced damage threshold - Classification of medical beam delivery systems (ISO 22248)	27 May 2024
22.	Cardiac rhythm management devices - Symbols to be used with cardiac rhythm management device labels, and information to be supplied - General requirements (ISO 27185)	27 May 2024
23.	Active implantable medical devices - Four-pole connector system for implantable cardiac rhythm management devices - Dimensional and test requirements (ISO 27186)	27 May 2024
24.	Medical electrical equipment - Part 4-5: Guidance and interpretation - Safety related technical security specifications for medical devices (IEC TR 60601-4-5)	27 May 2024
25.	Medical electrical equipment - Part 2-86: Particular requirements for the basic safety and essential	27 May 2024

	performance of electrocardiographs, including diagnostic equipment, monitoring equipment, ambulatory equipment, electrodes, cables and leadwires (IEC 80601-2-86)	
26.	Medical electrical equipment - Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children (IEC 80601-2-89)	27 May 2024
27.	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle (IEC 81001-5-1)	27 May 2024

ANNEX II

List of existing standards to be revised and list of new standards to be drafted as referred to in Article 1(2)

Table 1: List of existing harmonised standards to be revised and deadlines for the adoption of the revised harmonised standards

Reference information		Deadline for the adoption
1.	EN 556-1:2001+AC:2006 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	27 May 2024
2.	EN 556-2:2015 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices	27 May 2024
3.	EN ISO 7010:2012 Graphical symbols - Safety colours and safety signs - Registered safety signs	27 May 2024
4.	EN ISO 11135:2014+A1:2019 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	27 May 2024
5.	EN ISO 11137-1:2015+A2:2019 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	27 May 2024
6.	EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	27 May 2024
7.	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier	27 May 2024

	systems and packaging systems	
8.	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	27 May 2024
9.	EN ISO 11737-1:2018 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products	27 May 2024
10.	EN ISO 11737-2:2020 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	27 May 2024
11.	EN ISO 13408-1:2015 Aseptic processing of health care products - Part 1: General requirements	27 May 2024
12.	EN ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Filtration	27 May 2024
13.	EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization	27 May 2024
14.	EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies	27 May 2024
15.	EN ISO 13408-5:2011 Aseptic processing of health care products - Part 5: Sterilization in place	27 May 2024
16.	EN ISO 13408-6:2011+A1:2013 Aseptic processing of health care products - Part 6: Isolator systems	27 May 2024
17.	EN ISO 13408-7:2015	27 May 2024

	Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products	
18.	EN ISO 13485:2016+AC:2018 Medical devices - Quality management systems - Requirements for regulatory purposes	27 May 2024
19.	EN 13532:2002 General requirements for *in vitro* diagnostic medical devices for self-testing	27 May 2024
20.	EN 13612:2002+AC:2002 Performance evaluation of *in vitro* diagnostic medical devices	27 May 2024
21.	EN 13641:2002 Elimination or reduction of risk of infection related to *in vitro* diagnostic reagents	27 May 2024
22.	EN 13975:2003 Sampling procedures used for acceptance testing of *in vitro* diagnostic medical devices - Statistical aspects	27 May 2024
23.	EN 14136:2004 Use of external quality assessment schemes in the assessment of the performance of *in vitro* diagnostic examination procedures	27 May 2024
24.	EN ISO 14937:2009 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	27 May 2024
25.	EN ISO 14971:2019 Medical devices - Application of risk management to medical devices	27 May 2024
26.	EN ISO 15193:2009 *In vitro* diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference	27 May 2024

	measurement procedures	
27.	EN ISO 15194:2009 *In vitro* diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation	27 May 2024
28.	EN ISO 15197:2015 *In vitro* diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus	27 May 2024
29.	EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	27 May 2024
30.	EN ISO 17511:2003 *In vitro* diagnostic medical devices - requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples	27 May 2024
31.	EN ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices	27 May 2024
32.	EN ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	27 May 2024
33.	EN ISO 18113-1:2011 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements	27 May 2024
34.	EN ISO 18113-2:2011 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In*	27 May 2024

	vitro diagnostic reagents for professional use	
35.	EN ISO 18113-3:2011 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: *In vitro* diagnostic instruments for professional use	27 May 2024
36.	EN ISO 18113-4:2011 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: *In vitro* diagnostic reagents for self-testing	27 May 2024
37.	EN ISO 18113-5:2011 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: *In vitro* diagnostic instruments for self-testing	27 May 2024
38.	EN ISO 20857:2013 Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilization process for medical devices	27 May 2024
39.	EN ISO 23640:2015 *In vitro* diagnostic medical devices - Evaluation of stability of *in vitro* diagnostic reagents	27 May 2024
40.	EN ISO 25424:2019 Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices	27 May 2024
41.	EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	27 May 2024
42.	EN 61326-2-6:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - *In vitro* diagnostic (IVD) medical equipment	27 May 2024

43.	EN 61010-1:2010+A1:2019+AC:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements	27 May 2024
44.	EN 61010-2-101:2017 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for *in vitro* diagnostic (IVD) medical equipment	27 May 2024
45.	EN 62304:2006+A1:2015 Medical device software - Software life-cycle processes	27 May 2024
46.	EN 62366-1:2015+AC:2015+AC:2016+A1:2020 Medical devices - Application of usability engineering to medical devices	27 May 2024

Table 2: List of new harmonised standards to be drafted and deadlines for their adoption

Reference information		**Deadline for the adoption**
1.	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664-1)	27 May 2024
2.	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Medical devices not intended for direct patient contact (ISO 17664-2)	27 May 2024
3.	*In vitro* diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916)	27 May 2024

ANNEX III

Requirements for the standards referred to in Article 1

Part A. General requirements

1. Legal requirements to be supported by the harmonised standards

The harmonised standards shall support application of relevant safety and performance requirements for medical devices and *in vitro* diagnostic medical devices for human use and system and process requirements for economic operators and sponsors of clinical investigations and performance studies set out in Regulations (EU) 2017/745 and (EU) 2017/746.

The harmonised standards shall provide detailed technical, scientific, processual or methodological specifications of safety and performance requirements with the purpose of allowing compliance with relevant requirements of Regulations (EU) 2017/745 and (EU) 2017/746. Where appropriate, the harmonised standards shall include methods to verify compliance with such specifications.

The structure of a harmonised standard shall be such that a clear distinction can be made between its clauses and sub-clauses, which are necessary for compliance with the safety and performance requirements of Regulation (EU) 2017/745 or Regulation (EU) 2017/746 that the standard aims to cover and those which are not. The relationship between the clauses and sub-clauses of a harmonised standard and the requirements of Regulation (EU) 2017/745 or Regulation (EU) 2017/746 shall be indicated in the Annexes Z to each standard. The relevant requirements of Regulations (EU) 2017/745 and (EU) 2017/746 shall be taken into account from the beginning and throughout the process of developing of the standards.

The normative body of a harmonised standard shall not:

(a) make any references to Regulation (EU) 2017/745 or Regulation (EU) 2017/746 or reproduce their requirements;

(b) contradict any definitions set out in Regulations (EU) 2017/745 and (EU) 2017/746 or define any legally relevant terms not defined in those Regulations.

Where a definition in a harmonised standard differs from a definition of the same term set out in Regulation (EU) 2017/745 or Regulation (EU) 2017/746, the differences shall be indicated in the foreword of that standard and in its Annex Z. That Annex shall also state that, for the purpose of using the standard in support of the requirements set out in Regulations (EU) 2017/745 and (EU) 2017/746, the definitions set out in those Regulations prevail.

Each harmonised standard developed on the basis of the standardisation request referred to in Article 1 shall refer to this Decision.

Each revised harmonised standard shall contain information on significant changes introduced in that standard.

2. Legal requirements to be covered by an individual harmonised standard

When one of the harmonised standards listed in Annex I or in Annex II does not cover all relevant requirements applicable to devices or system or process requirements falling under its scope, or when it covers such requirements only partially, that standard shall include in its Annex Z information on the relevant applicable requirements or parts thereof that are not covered by it.

Where appropriate, the harmonised standard shall include information as to whether a particular requirement is addressed with regard to the design, manufacturing, or packaging of the device.

3. Reduction of risk

The specifications of harmonised standards concerning the reduction of risk which may be associated with the device shall take into account the general requirements laid down in point 2 of Chapter I of Annex I to Regulation (EU) 2017/745 and in point 2 of Chapter I of Annex I to Regulation (EU) 2017/746 to reduce risks as far as possible without adversely affecting the benefit-risk ratio.

4. Normative references

Normative references included in a harmonised standard shall be clear and specific and ensure identification of all specifications covered by the standard. Where a standard refers to another standard or a clause in that standard, and that standard or clause contains a further normative reference or references ('a normative reference chain'), the whole normative reference chain shall be clear and specific. Normative reference chains shall be avoided.

Clauses of a standard, which do not provide for technical, scientific or methodological specifications, but are limited to a normative reference to another standard or a clause in that standard shall not claim coverage of the legal requirements that are addressed in the standard normatively referred to.

Standards which do not ensure compliance with legal requirements on their own, but require application of another standard, shall contain a clear statement to that effect. They shall not claim coverage of the legal requirements covered by that other standard.

Standards containing normative references to undated standards shall indicate the dated version of any such referenced standard.

5. Publicly available description of the meaning of symbols

Where a harmonised standard provides a description of the meaning of symbols to be used in the information supplied by the manufacturer that description shall be made publicly available. Public availability of such descriptions shall not affect any copyright to a harmonised standard or its parts.

Part B. Specific requirements

1. Requirements for all harmonised standards listed in Annexes I and II

The harmonised standards shall ensure safety and effectiveness of devices and a high level of protection of health and safety of patients, users or others persons. They shall reflect the generally acknowledged state of the art.

2. Requirements for certain specific standards listed in Annexes I and II

2.1 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (EN ISO 10993-7:2008+AC:2009) and Part 17: Establishment of allowable limits for leachable substances (EN ISO 10993-17:2009)

In the standard EN ISO 10993-7:2008+AC:2009, the method of calculation of residue limits for ethylene oxide sterilant laid down in point 4.3.1 of that standard shall be modified in such a way as to take into account also patients with a weight lower/higher

than 70 kg, in particular neonates and other patients with a weight substantially below the adults' standard weight of 70 kg.

In the standard EN ISO 10993-17:2009, the method of calculation of concomitant exposure to ethylene oxide sterilant laid down in points 6.2.2 and 6.3.2 of that standard shall be modified in such a way as to take into account certain clinical situations involving use of several medical devices in neonates with a bodyweight lower than 3,5 kg.

2.2 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (EN ISO 15223-1:2016)

The existing standard EN ISO 15223-1:2016 shall be modified by the addition of a symbol which indicates that a device is a medical device or an *in vitro* diagnostic medical device to facilitate application of section 23.2(q) of Chapter III of Annex I to Regulation (EU) 2017/745 or section 20.2(e) of Chapter III of Annex I to Regulation (EU) 2017/746, as appropriate.

2.3 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling (EN ISO 23908:2013)

The existing standard EN ISO 23908:2013 shall be modified by describing technical solutions for safety-engineered mechanisms to be applied in design and manufacture of devices to ensure compliance with points 11.1 and 22.2 of Chapter II of Annex I to Regulation (EU) 2017/745. The standard shall apply to devices which are intended to be used for administration and/or extraction of body/blood fluids and/or medicinal substances.

2.4 Health software - Part 1: General requirements for product safety (EN 82304-1:2017)

The existing standard EN 82304-1:2017 shall be modified by ensuring a clear separation between products (software) which fall within the scope of Regulation (EU) 2017/745 and those that do not, ensuring that there is no ambiguity on its legal effect and on which products could claim presumption of conformity on its basis.