EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Policy, Regulation and Implementation
Standards for Growth

Brussels, 26.6.2019

A Notification under Article 12 of Regulation (EU) No 1025/2012[1]

Subject matter related to

☐	Annual Union Work Programme for European standardisation (Art. 12, point a)
☒	Possible future standardisation requests to the European standardisation organisations (Art. 12, point b)
☐	Formal objections to harmonised standards (Art. 12, point c)
☐	Identifications of ICT technical specifications (Art. 12, point d)
☐	Delegated acts to modify Annexes I or III of Regulation (EU) No 1025/2012 (Art. 12, point e)

Title of the initiative

Draft standardisation request to the European Committee for Standardisation 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

Additional information

Legislative reference(s)	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; 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
EN reference(s)	-
Status	Draft
Other information	-
Deadline for feedback	25.7.2019

Commission contact point for this notification

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

COMMISSION IMPLEMENTING DECISION

of XXX

on a standardisation request to the European Committee for Standardisation 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 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.

(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 harmonised standards or parts thereof, the references of which have

[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).

been published in the *Official Journal of the European Union*, are to be presumed to be in conformity with the requirements of the Regulations covered by those standards or parts thereof.

(3) Voluntary harmonised standards should help to ensure high level of protection of health 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 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, and clinical investigation and performance studies. The Regulations 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) In accordance with point 1 of Chapter I in Annex I to Regulation (EU) 2017/745 and point 1 of Chapter I in Annex I 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 standards should support the attainment of these objectives.

(6) On the basis of several standardisation mandates issued by the Commission, the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) have drafted harmonised standards in support of Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC. These harmonised standards need to be revised to take into account the requirements set out in Regulation (EU) 2017/745 and Regulation (EU) 2017/746 and the need to specify the correspondence between the technical specifications included in the standards and the requirements of the Regulations they aim to cover. In addition, some additional standards developed at international level need to be adapted to the EU legal framework or some new standards need to be drafted.

(7) The intention to request review or update of the existing harmonised standards and drafting of new standards in support of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 is stated in point 18 of the Commission Staff Working Document

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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).

accompanying the annual Union work programme for European standardisation for 2018[7].

(8) CEN and Cenelec have indicated that the work covered by this Decision falls within their area of competence.

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

(10) The references to standards listed in Table 1 of Annex I and Table 1 of Annex II correspond with the most recent versions of those standards published by CEN and Cenelec on the date of this Decision. CEN and Cenelec should promptly inform the Commission about any subsequent version of a standard published after the date of this Decision, including any amendments to the standard.

(11) Given the number and varying subject matter of the existing harmonised standards in support of Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC, this Decision should cover horizontal standards addressing the needs of the widest scope of different economic operators and to allow a subsequent alignment of semi-horizontal and device-specific standards which may derive from or complement the horizontal standards. Additional system or process standards may be also needed in the future.

(12) Depending on the progress of the implementation of the work programme of CEN and Cenelec, it may be necessary to consider adding new items to the lists of standards set out in Annexes I and II to this Decision, to address any arising standardisation needs, in particular as regards semi-horizontal or device-specific standards or additional system or process standards. CEN and Cenelec should inform the Commission if they consider that additional standards would need to be developed. It may be also necessary to consider adding new items to the list of standards set out in Annexes I and II to this Decision taking into account any needs newly identified by Member States and the European stakeholder organisations receiving Union financing in accordance with Regulation (EU) No 1025/2012. It may therefore be necessary to adjust the scope of this request accordingly.

(13) Harmonised standards should include detailed technical specifications in relation to the requirements of Regulation (EU) 2017/745 and Regulation (EU) 2017/746, especially with respect to the design and manufacture of devices, risk management, and requirements to be fulfilled by sponsors, including those relating to quality management systems, risk management, clinical investigations and performance studies, and clinical evaluation and clinical evidence.

(14) In accordance with Section 23.1(h) of Chapter III in Annex I to Regulation (EU) 2017/745 and Section 20.1(h) of Chapter III in 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 (CS). Moreover, the use of symbols in device information is to take into account the intended users. In order to ensure that users 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 part.

[7] SWD(2017) 284 final of 25 August 2017.

(15) CEN and Cenelec should follow the Guidelines for the execution of standardisation requests[8].

(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. 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.

(17) Information as to which legal requirements are covered or partially covered by a standard to be harmonised is necessary when assessing, in accordance with Article 10(5) of Regulation (EU) 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) 1025/2012. In each harmonised standard, CEN and Cenelec should therefore specify the extent to which the technical specifications included in the standard aim to cover one or several requirements set out in Regulation (EU) 2017/745 or Regulation (EU) 2017/746.

(18) The standards should be adopted by CEN and Cenelec by the deadlines set in this Decision. Given that the execution of the request may require more time than initially foreseen, it may be necessary to extend those deadlines taking into account the progress made in the implementation of the work programme prepared by CEN and Cenelec for the execution of the request, and any related standardisation work undertaken by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). It may therefore be necessary to review the respective deadlines accordingly.

(19) In accordance with Article 10(3) of Regulation (EU) No 1025/2012 standardisation request is subject to acceptance by the relevant European standardisation organisation. It is therefore necessary to provide for the rules on 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. If the deadlines for adoption of standards are extended, it may be necessary to extend the date of expiry of this Decision, taking into account the progress made in the implementation of the work programme prepared by CEN and Cenelec for the execution of the request.

(21) Harmonised standards should reflect state of the art. CEN and Cenelec should inform the Commission without delay about the need to withdraw or revise any standard developed on the basis of this Decision.

(22) Given that Directive 90/385/EEC and Directive 93/42/EEC will be repealed as of 26 May 2020 and Directive 98/79/EC will be repealed as of 26 May 2022, any relevant standardisation mandates that have been issued by the Commission should not be used to develop standards in support of those Directives after those dates.

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

(23) The European standardisation organisations, the European stakeholders' organisations receiving Union financing and the Medical Device Coordination Group established by Article 103(1) of Regulation (EU) 2017/745 have been consulted.

(24) 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 Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) are requested to revise the existing standards listed in Table 1 of Annex I to this Decision and to draft new standards listed in Table 2 of that Annex in support of Regulation (EU) 2017/745.

2. CEN and Cenelec are requested to revise the existing standards listed in Table 1 of Annex II to this Decision and to draft new standards listed in Table 2 of that Annex in support of Regulation (EU) 2017/746.

3. If, after the date of this Decision and prior to execution of the present request for any particular standard listed in Table 1 of Annex I or Table 1 in Annex II, CEN or Cenelec publishes a new version of that standard or an amendment to that standard, it shall consult the Commission as to whether the new version of the standard could be used as a basis for execution of the request, and whether a modification of Annex I or Annex II is needed.

4. The standards referred to in the first and second paragraph shall meet the requirements set out in Annex III.

Article 2
Work programme

CEN and Cenelec shall prepare a draft joint work programme indicating all the standards referred to 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. They shall submit the draft joint work programme to the Commission by *[insert date – 6 weeks after notification of this Decision by the Commission]*.

CEN and Cenlec shall inform the Commission of any amendments to the work programme.

During the validity of this standardisation request, CEN and Cenelec shall provide the Commission with access to an overall project plan containing up to date information on specific work items necessary for the execution of the standardisation request.

Article 3
Reporting

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

2. They shall submit the first annual joint report to the Commission by *[insert date – 12 months after notification of this Decision by the Commission]*.

3. Subsequent annual reports shall be submitted to the Commission by 31 October each year.

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

5. Without prejudice to the reporting obligations set out in paragraphs 1 to 4, CEN and Cenelec shall promptly report to the Commission any major concerns relating to the deadlines set out in Annexes I and II.

Article 4
Development of standards

1. CEN and Cenelec shall include in each standard a clear and precise description of the relationship between its content and the corresponding requirements set out in Regulation (EU) 2016/745 or Regulation (EU) 2016/746 that it aims to cover.

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

3. CEN and Cenelec shall include in each existing standard revised in accordance with Article 1 information on significant changes introduced in the standard following the revision of the standard on the basis of this Decision.

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

Article 5
State of the art

CEN and Cenelec shall inform the Commission without delay about the need to withdraw or revise any standard developed on the basis of this Decision, taking into account the development of the state of the art.

Article 6
Validity of the standardisation request

If CEN or Cenelec do not accept the 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 7
Existing standardisation mandates

1. As of 26 May 2020, the following standardisation mandates shall not constitute a basis for development of harmonised standards in support of Directive 90/385/EEC, Directive 93/42/EEC:

   (a) M/BC/CEN/CLC/9/89 of 19 December 1991;

   (b) M/BC/CEN/91/3;

   (c) M/295 of 9 September 1999;

   (d) M/321 of 13 June 2002;

(e) M/333 of 23 October 2003;

(f) M/342 of 10 February 2004;

(g) M/432 of 24 November 2008;

(h) M/433 of 24 November 2008;

(i) M/467 of 19 May 2010.

2. As of 26 May 2022, the following standardisation mandates shall not constitute a basis for development of harmonised standards in support of Directive 98/79/EC:

(a) M/252 of 12 September 1997;

(b) M/321 of 13 June 2002;

(c) M/384 of 6 April 2006.

Article 8
Addressees

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

Done at Brussels,

For the Commission
Elżbieta Bieńkowska
Member of the Commission

ANNEX I

List of existing standards to be revised and list of new standards to be drafted in support of Regulation (EU) 2017/745 as referred to in Article 1(1)

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

Reference information		Deadline for the adoption[1] by the ESOs
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	27/5/2024
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	27/5/2024
3.	EN ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	27/5/2024
4.	EN ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	27/5/2024
5.	EN ISO 10993-4:2017 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	27/5/2024
6.	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	27/5/2024
7.	EN ISO 10993-6:2016 Biological evaluation of medical devices - Part 6:	27/5/2024

[1] 'Adoption' refers to the relevant European standardisation organisation making an adopted standard available to its members or the public.

	Tests for local effects after implantation	
8.	EN ISO 10993-7:2008+AC:2009 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	27/5/2024
9.	EN ISO 10993-9:2009 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	27/5/2024
10.	EN ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	27/5/2024
11.	EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	27/5/2024
12.	EN ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	27/5/2024
13.	EN ISO 10993-13:2010 Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	27/5/2024
14.	EN ISO 10993-14:2009 Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	27/5/2024
15.	EN ISO 10993-15:2009 Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	27/5/2024
16.	EN ISO 10993-16:2017 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	27/5/2024

17.	EN ISO 10993-17:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	27/5/2024
18.	EN ISO 10993-18:2009 Biological evaluation of medical devices - Part 18: Chemical characterization of materials	27/5/2024
19.	EN ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	27/5/2024
20.	EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	27/5/2024
21.	EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	27/5/2024
22.	EN ISO 11607-1:2017 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	27/5/2024
23.	EN ISO 11607-2:2017 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	27/5/2024
24.	EN ISO 11737-1:2018 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products	27/5/2024
25.	EN ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the	27/5/2024

	definition, validation and maintenance of a sterilization process	
26.	EN ISO 13408-1:2015 Aseptic processing of health care products - Part 1: General requirements	27/5/2024
27.	EN ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Filtration	27/5/2024
28.	EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization	27/5/2024
29.	EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies	27/5/2024
30.	EN ISO 13408-5:2011 Aseptic processing of health care products - Part 5: Sterilization in place	27/5/2024
31.	EN ISO 13408-6:2011+A1:2013 Aseptic processing of health care products - Part 6: Isolator systems	27/5/2024
32.	EN ISO 13408-7:2015 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products	27/5/2024
33.	EN ISO 13485:2016+AC:2018 Medical devices - Quality management systems - Requirements for regulatory purposes	26/5/2020
34.	EN ISO 14155:2011+AC:2011 Clinical investigation of medical devices for human subjects - Good clinical practice	26/5/2020
35.	EN ISO 14160:2011 Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices	27/5/2024

	utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	
36.	EN ISO 14630:2012 Non-active surgical implants - General requirements	27/5/2024
37.	EN 14885:2018 Chemical disinfectants and antiseptics - Application of European standards for chemical disinfectants and antiseptics	27/5/2024
38.	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	27/5/2024
39.	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices	26/5/2020
40.	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	26/5/2020
41.	EN 15986:2011 Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates	26/5/2020
42.	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	27/5/2024
43.	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	27/5/2024

	devices	
44.	EN ISO 22442-1:2015 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management	27/5/2024
45.	EN ISO 22442-2:2015 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling	27/5/2024
46.	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	27/5/2024
47.	EN ISO 25424:2011 Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices	27/5/2024
48.	EN 60601-1:2006 + AC:2010 + A1:2013+A12:2014 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	27/5/2024
49.	EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	27/5/2024
50.	EN 60601-1-3:2008+AC:2010+A11:2016 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	27/5/2024
51.	EN 60601-1-6:2010+A1:2015 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential	27/5/2024

	performance - Collateral standard: Usability	
52.	EN 60601-1-8:2007+AC:2010+A11:2017+prA2 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	27/5/2024
53.	EN 60601-1-10:2008+A1:2015 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	27/5/2024
54.	EN 60601-1-11:2015 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	27/5/2024
55.	EN 60601-1-12:2015 Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	27/5/2024
56.	EN 62304:2018 Medical device software - Software life-cycle processes	27/5/2024
57.	EN 62366-1:2015+AC:2016 Medical devices - Application of usability engineering to medical devices	27/5/2024

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

Reference information		Deadline for the adoption by the ESOs
1.	prEN ISO 10993-23 Biological evaluation of medical devices - Part 23: Determination of skin irritation of medical device extracts using Reconstructed human Epidermis (RhE) (ISO 10993-23)	27/5/2024
2.	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)	27/5/2024
3.	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664-1)	27/5/2024
4.	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)	27/5/2024
5.	prEN ISO 20417 Medical devices – Information to be provided by manufacturer (ISO 20417)	27/5/2024
6.	Sharps injury protection – Requirements and test methods – Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling (ISO 23908)	27/5/2024

ANNEX II

List of existing standards to be revised and list of new standards to be drafted in support of Regulation (EU) 2017/746 as referred to in Article 1(2)

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

Reference information		Deadline for the adoption by the ESOs
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	27/5/2024
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	27/5/2024
3.	EN ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	27/5/2024
4.	EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	27/5/2024
5.	EN ISO 11607-1:2017 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	27/5/2024
6.	EN ISO 11607-2:2017 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	27/5/2024
7.	EN ISO 11737-1:2018 Sterilization of medical devices - Microbiological	27/5/2024

	methods - Part 1: Determination of a population of microorganisms on products	
8.	EN ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	27/5/2024
9.	EN ISO 13408-1:2015 Aseptic processing of health care products - Part 1: General requirements	27/5/2024
10.	EN ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Filtration	27/5/2024
11.	EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization	27/5/2024
12.	EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies	27/5/2024
13.	EN ISO 13408-5:2011 Aseptic processing of health care products - Part 5: Sterilization in place	27/5/2024
14.	EN ISO 13408-6:2011+A1:2013 Aseptic processing of health care products - Part 6: Isolator systems	27/5/2024
15.	EN ISO 13408-7:2015 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products	27/5/2024
16.	EN ISO 13485:2016+AC:2018 Medical devices - Quality management systems - Requirements for regulatory purposes	26/5/2020
17.	EN 13532:2002	27/5/2024

	General requirements for in vitro diagnostic medical devices for self-testing	
18.	EN 13612:2002+AC:2002 Performance evaluation of in vitro diagnostic medical devices	27/5/2024
19.	EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents	27/5/2024
20.	EN 13975:2003 Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects	27/5/2024
21.	EN 14136:2004 Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures	27/5/2024
22.	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	27/5/2024
23.	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices	26/5/2020
24.	EN ISO 15193:2009 In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures	27/5/2024
25.	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	27/5/2024
26.	EN ISO 15197:2015	27/5/2024

	In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus	
27.	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	26/5/2020
28.	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	27/5/2024
29.	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	27/5/2024
30.	EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements	30/9/2021
31.	EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use	30/9/2021
32.	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	30/9/2021
33.	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	30/9/2021
34.	EN ISO 18113-5:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In	30/9/2021

	vitro diagnostic instruments for self-testing	
35.	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	27/5/2024
36.	EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents	27/5/2024
37.	EN ISO 25424:2011 Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices	27/5/2024
38.	EN 62304:2018 Medical device software - Software life-cycle processes	27/5/2024
39.	EN 62366-1:2015+AC:2016 Medical devices - Application of usability engineering to medical devices	27/5/2024

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

Reference information		**Deadline for the adoption by the ESOs**
1.	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664-1)	27/5/2024
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)	27/5/2024
3.	In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916)	26/5/2022

4.	prEN ISO 20417 Medical devices – Information to be provided by manufacturer (ISO 20417)	27/5/2024

ANNEX III

Requirements for the standards referred to in Article 1(1) and (2)

Part A. General requirements for standards listed in Annexes I and II

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 Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

The harmonised standards shall provide detailed technical, scientific or methodological specifications with the purpose of allowing compliance with relevant requirements of the Regulations. The specifications shall be in conformity with the Regulations. Where appropriate, the specifications shall include methods for the verification of compliance with such specifications.

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

Harmonised standards shall not:

– make any references to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 or reproduce their requirements in the normative body;

– modify any definitions set by Regulation (EU) 2017/745 and Regulation (EU) 2017/746 or define any legally relevant terms not defined in those Regulations;

– without prejudice to Article 9(1) Regulation (EU) 2017/745 and Article 9(1) Regulation (EU) 2017/746, lay down specifications concerning the requirements of the Regulations that may be subject of implementing acts of the Commission, in accordance with the empowerments laid down in those Regulations;

– contain any provisions concerning conformity assessment procedures, related documents or technical file as regulated by Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

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

When a standard does not cover all relevant requirements, which are applicable to devices or system or process requirements under its scope, or it covers such requirements only partially, the standard shall include information on the relevant applicable requirements or parts of the relevant applicable requirements that are not covered by it. Where appropriate, the standard shall include information as to whether a particular requirement is addressed with regard to the design, manufacturing, or packaging of the device.

3. High level of protection of health and safety, state of the art and risk reduction methodologies

The specifications for design, manufacture and packaging of devices, system or process requirements shall guarantee safety and effectiveness of devices and high level of protection

of health and safety of patients, users or others persons. They shall reflect the generally acknowledged state of the art.

The specifications concerning the reduction of risk which may be associated with the device shall take into account the general requirement laid down in point 2 of Chapter I in Annex I to Regulation (EU) 2017/745 and in point 2 of Chapter I in 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 the standard shall be clear and specific, to ensure identification of all specifications thus covered by the standard. Where a standard normatively 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. In general, in order to ensure consistency and accuracy of the normative references, normative reference chains should 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 which require application of another standard, shall contain a clear statement to that effect. Accordingly, they shall not claim coverage of the legal requirements covered by another standard.

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

5. Correspondence between the clauses of the standard and the legal requirements

CEN and Cenelec shall include in each standard the information on the correspondence between the clauses of the standard and the requirements of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 aimed to be covered. Only the clauses covered by that correspondence can support application of the requirements set out in the Regulations.

6. Publicly available description of the meaning of symbols used in the information supplied by the manufacturer

CEN and Cenelec shall ensure, for instance by means of a notice on their websites, publicly available description of the meaning of symbols to be used in the information supplied by the manufacturer of the device that are defined by any standard subject to the present request if that standard becomes harmonised under Regulation (EU) 2017/745 or Regulation (EU) 2017/746. Public availability of such descriptions shall not affect any copyright to a harmonised standard or its part.

Part B. Specific requirements for standards listed in Annexes I and II

1. Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (10993-7:2008+AC:2009) and Part 17: Biological evaluation of medical devices - 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 shall be modified in such a way as to take into account also patients other than those of the 70 kg of weight, 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 the harmonised standard EN ISO 10993-17 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. 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)

CEN shall revise the existing standard by adding 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 in Annex I to Regulation (EU) 2017/745 or Section 20.2(e) of Chapter III in Annex I to Regulation (EU) 2017/746, as appropriate.

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 (ISO 23908)

CEN shall draft a standard 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 in Chapter II of Annex I to Regulation (EU) 2017/745. The standard shall apply to devices which intended use is the administration and/or extraction of body/blood fluids and/or medicinal substances.