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

Ecosystems III: Construction & machinery
Standards Policy

Brussels, 1.6.2022

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 amending Implementing Decision C(2021) 2406 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

Additional information

Legislative/Policy reference(s)	Regulation (EU) 2017/745, Regulation (EU) 2017/746
EN reference(s)	-
Status	Draft
Other information	This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.
Deadline for feedback	30.6.2022

Commission contact point for this notification

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

Brussels, XXX
[…](2022) XXX draft

COMMISSION IMPLEMENTING DECISION

of XXX

amending Implementing Decision C(2021) 2406 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)

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amending Implementing Decision C(2021) 2406 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] replacing Council Directive 90/385/EEC[3] and Council Directive 93/42/EEC[4] 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[5] replacing Directive 98/79/EC of the European Parliament and of the Council[6] 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

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 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).

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

5 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).

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).

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) By Implementing Decision C(2021) 2406[7], the Commission made a request to the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) for the revision of existing harmonised standards on medical devices developed in support of Directives 90/385/EEC and 93/42/EEC and the drafting of new harmonised standards in support of Regulation (EU) 2017/745; and for the revision of existing harmonised standards on *in vitro* diagnostic medical devices developed in support of Directive 98/79/EC and the drafting of new harmonised standards on support of Regulation (EU) 2017/746.

(4) CEN and CENELEC have indicated that the work covered by the standardisation request falls within their area of competence, and accepted the request. Accordingly, having agreed to follow the Guidelines for the execution of standardisation requests[8], CEN and CENELEC prepared a joint work programme and submitted it to the Commission.

(5) CEN and CENELEC have regularly reported to the Commission on the execution of the standardisation request, and already adopted a number of revised or new harmonised standards in support of Regulation (EU) 2017/745 and of Regulation (EU) 2017/746. After the assessment of those standards to check whether they comply with the request set out in Implementing Decision C(2021) 2406, the Commission published the references of those standards in the *Official Journal of the European Union*.

(6) At the same time, taking into account that, during the execution of the standardisation request, it may be necessary to adjust the scope of the request or the deadline set therein, CEN and CENELEC reported to the Commission that it is appropriate to adapt the scope of the request by adding certain standardisation items and by removing certain others, in order to take into account the latest technical and scientific progress, as well as the latest developments of standardisation activities in the field of medical devices at international and European levels.

(7) The references of the standards EN ISO 1135-4:2015 on transfusion equipment for medical use, EN ISO 1135-5:2015 on transfusion equipment for medical use and EN ISO 10651-4:2009 on lung ventilators should be included in the list of existing harmonised standards to be revised in support of Regulation (EU) 2017/745 laid down in Table 1 of Annex I to Implementing Decision C(2021) 2406.

(8) The references of the standards prEN 1865-6 on patient handling equipment used in road ambulances, EN ISO 11737-3 on sterilization of health care products, ISO 13004 on sterilization of health care products, ISO 18362:2016/DAMD1 on manufacture of cell-based health care products, EN ISO 22441 on sterilization of health care products, prEN ISO 80369 on small-bore connectors for liquids and gases in healthcare applications, prEN ISO 80601-2-84 on medical electrical equipment, and of a standard

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7 Commission Implementing Decision C(2021) 2406 of 14 April 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.

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

on respiratory infection prevention devices for self- and third party protection, should be included in the list of new harmonised standards to be drafted in support of Regulation (EU) 2017/745 laid down in Table 2 of Annex I to Implemnting Decision C(2021) 2406.

(9) The references of the standards ISO 9978 on radiation protection, ISO 14117 on active implantable medical devices, ISO 14708-1 on implants for surgery, ISO 27185 on cardiac rhythm management devices, ISO 27186 on active implantable medical devices and IEC TR 60601-4-5 on medical electrical equipment should be removed from the list of new harmonised standards to be drafted in support of Regulation (EU) 2017/745 laid down in Table 2 of Annex I to Implemnting Decision C(2021) 2406.

(10) The references of the standards EN ISO 11737-3 on sterilization of health care products, ISO 13004 on sterilization of health care products, ISO 18362:2016/DAMD1 on manufacture of cell-based health care products, and EN ISO 22441 on sterilization of health care products, should be included in the list of new harmonised standards to be drafted in support of Regulation (EU) 2017/746 laid down in Table 2 of Annex II to Implemnting Decision C(2021) 2406.

(11) Implementing Decision C(2021) 2406 should therefore be amended accordingly.

(12) 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.

(13) 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

Implementing Decision C(2021) 2406 is amended as follows:

Annexes I and II to Implementing Decision C(2021) 2406 are amended in accordance with the Annex to this Decision.

Article 2

If CEN or CENELEC do not accept the amendments set out in Article 1 of this Decision in accordance with Article 10(3) of Regulation (EU) No 1025/2012, this Decision shall cease to apply and Implementing Decision C(2021) 2406 in its version of 14 April 2021 shall continue to apply for the standardisation organisation concerned.

Article 3

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

Done at Brussels,

For the Commission

ANNEX

1. Annex I is amended as follows:

(1) in Table 1, the following entry is added:

Reference information		Deadline for the adoption
‘202.	EN ISO 1135-4:2015 Transfusion equipment for medical use - Part 4: Transfusion sets for single use, gravity feed	27 May 2024
203.	EN ISO 1135-5:2015 Transfusion equipment for medical use - Part 5: Transfusion sets for single use with pressure infusion apparatus	27 May 2024
204.	EN ISO 10651-4:2009 Lung ventilators - Part 4: Particular requirements for user-powered resuscitators	27 May 2024’.

(2) in Table 2, the following entries are added:

Reference information		Deadline for the adoption
‘28.	Patient handling equipment used in road ambulances - Part 6: Power assisted chairs (prEN 1865-6)	27 May 2024
29.	Sterilization of health care products - Microbiological methods - Part 3: Bacterial endotoxin testing (EN ISO 11737-3)	27 May 2024
30.	Sterilization of health care products - Radiation - Substantiation of selected sterilization dose: Method VDmaxSD (ISO 13004)	27 May 2024
31.	Manufacture of cell-based health care products - Control of microbial risks during processing - Amendment 1 (ISO 18362:2016/DAMD 1)	27 May 2024
32.	Sterilization of health care products - Low temperature vaporized hydrogen peroxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (EN ISO 22441)	27 May 2024
33.	Small-bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for	27 May 2024

	respiratory applications (ISO/DIS 80369-2:2021) (prEN ISO 80369)	
34.	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment (prEN ISO 80601-2-84)	27 May 2024
35.	Respiratory infection prevention devices for self- and third party protection - Requirements for different performance classes and test methods	27 May 2024'.

(3) In Table 2, the following entries are removed:

Reference information		**Deadline for the adoption**
'2.	Radiation protection - Sealed radioactive sources - Leakage test methods (ISO 9978)	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
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
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'.

2. Annex II is amended as follows:

In Table 2, the following entry is added:

Reference information		Deadline for the adoption
‘4.	Sterilization of health care products - Microbiological methods - Part 3: Bacterial endotoxin testing (EN ISO 11737-3)	27 May 2024
5.	Sterilization of health care products - Radiation - Substantiation of selected sterilization dose: Method VDmaxSD (ISO 13004)	27 May 2024
6.	Manufacture of cell-based health care products - Control of microbial risks during processing - Amendment 1 (ISO 18362:2016/DAMD 1)	27 May 2024
7.	Sterilization of health care products - Low temperature vaporized hydrogen peroxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (EN ISO 22441)	27 May 2024’.