EUROPEAN
COMMISSION

Brussels, 27.5.2024
C(2024) 3371 final

COMMISSION IMPLEMENTING DECISION

of 27.5.2024

amending Implementing Decision C(2021) 2406 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, as regards the scope and validity of the request and the deadlines for the joint final report and for the adoption of certain harmonised standards, certain general requirements and the requirements for certain specific standards

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

COMMISSION IMPLEMENTING DECISION

of 27.5.2024

amending Implementing Decision C(2021) 2406 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, as regards the scope and validity of the request and the deadlines for the joint final report and for the adoption of certain harmonised standards, certain general requirements and the requirements for certain specific standards

(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) By Implementing Decision C(2021) 2406[2], 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 Council Directives 90/385/EEC[3] and 93/42/EEC[4], for the drafting of new harmonised standards in support of Regulation (EU) 2017/745 of the European Parliament and of the Council[5], for the revision of existing harmonised standards on *in vitro* diagnostic medical devices

1 OJ L 316, 14.11.2012, p. 12, ELI: http://data.europa.eu/eli/reg/2012/1025/oj.

2 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.

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, ELI: http://data.europa.eu/eli/dir/1990/385/oj).

4 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1, ELI: http://data.europa.eu/eli/dir/1993/42/oj).

5 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, ELI: http://data.europa.eu/eli/reg/2017/745/oj).

developed in support of Directive 98/79/EC of the European Parliament and of the Council[6], and for the drafting of new harmonised standards in support of Regulation (EU) 2017/746 of the European Parliament and of the Council[7] (the 'request').

(2) CEN and CENELEC have accepted the request and the standardisation work is ongoing.

(3) Implementing Decision C(2021) 2406 was amended by Implementing Decision C(2023) 694[8] to adapt the scope of the request by adding certain standardisation items and removing certain others.

(4) CEN and CENELEC informed the Commission that it is necessary to further adapt the scope of the request by adding certain standardisation items and removing certain others, in order to take into account the latest technical and scientific progress, as well as the latest developments in standardisation activities in the field of medical devices at international and European level.

(5) The Commission examined the information provided by CEN and CENELEC.

(6) Harmonised standards EN 13624, EN 13727, EN 14348, EN 14476, EN 14561, EN 14562, EN 14563, EN 16615, EN 16616, EN 16777, EN 17111, EN 17126 and EN 17387 on chemical disinfectants and antiseptics, EN ISO 17510 on sleep apnoea breathing therapy, EN ISO 23328-1 and EN ISO 23328-2 on breathing system filters for anaesthetic and respiratory use, EN ISO 23747 and EN ISO 26782 on anaesthetic and respiratory equipment, EN IEC 60601-2-22, EN IEC 60601-2-57 and EN IEC 80601-2-77 on medical electrical equipment, and EN IEC 61010-2-040 on safety requirements for electrical equipment for measurement, control, and laboratory use, need to be revised to take into account the requirements set out in Regulation (EU) 2017/745.

(7) New harmonised standards on anaesthetic reservoir bags (EN ISO 5362), on anaesthetic and respiratory equipment (EN ISO 5367, ISO 17256, ISO 18190, ISO 19211 and EN ISO 20789), on medical gas pipeline systems (EN ISO 7396-3), on lung ventilators for medical use (EN ISO 10651-5), on sterilization of health care products (EN ISO 11140-6), on washer-disinfectors (EN ISO 15883-5), on systems for evacuation of plume generated by medical devices (EN ISO 16571), on transportable liquid oxygen systems for medical use (EN ISO 18777-1 and EN ISO 18777-2), on clinical evaluation of medical devices (EN ISO 18969), and on medical electrical equipment (EN ISO 80601-2-55, EN ISO 80601-2-61, EN ISO 80601-2-67, EN ISO 80601-2-70, EN ISO 80601-2-72, EN ISO 80601-2-74, EN ISO 80601-2-79, EN ISO 80601-2-80, EN ISO 80601-2-85, EN ISO 80601-2-87 and EN ISO 80601-2-90), need to be drafted to support Regulation (EU) 2017/745.

---

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, ELI: http://data.europa.eu/eli/dir/1998/79/oj).

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, ELI: http://data.europa.eu/eli/reg/2017/746/oj).

8 Commission Implementing Decision C(2023) 694 of 31 January 2023 amending Implementing Decision C(2021) 2406 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) Standard EN 455-5 on medical gloves for single use is no longer to include requirements in relation to Regulation (EU) 2017/745, and so the project is intended to be de-linked from the harmonisation process. Therefore, reference to that standard should be deleted from the list of new harmonised standards to be developed in support of Regulation (EU) 2017/745 set out in Table 2 of Annex I to Implementing Decision C(2021) 2406.

(9) Standard EN 61010-1 on safety requirements for electrical equipment for measurement, control, and laboratory use is intended to be replaced by standard EN 61010-2-101, which is to include all the relevant content of the standard EN 61010-1. Therefore, references to this standard should be deleted from the list of existing harmonised standards to be revised in support of Regulation (EU) 2017/746 set out in Table 1 of Annex II to Implementing Decision C(2021) 2406.

(10) The scope of the standard on manufacture of cell-based health care products (ISO 18362) is intended to exclude devices falling within the scope of Regulation (EU) 2017/746. Therefore, references to that standard should be deleted from the list of new harmonised standards to be drafted in support of Regulation (EU) 2017/746 set out in Table 2 of Annex II to Implementing Decision C(2021) 2406.

(11) CEN and CENELEC informed the Commission on the progress of the standardisation work in response to the request, noting that it would not be possible to comply with the deadlines established for the adoption of certain harmonised standards, due to limitations in resources affecting the activities of the relevant technical committees in CEN and CENELEC at European level, and of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) at international level, as well as to some delays in the operation of the Harmonised Standards (HAS) consultant system for the assessment of draft harmonised standards.

(12) Moreover, the transitional periods provided for in Regulations (EU) 2017/745 and (EU) 2017/746, during which certain devices that are in conformity with Directive 90/385/EEC or Directive 93/42/EEC may lawfully be placed on the market, have been extended to 31 December 2028 for some of those devices.

(13) It is therefore appropriate to extend the deadline for CEN and CENELEC to provide the Commission with the joint final report to 30 June 2028, to extend the validity of the request to 31 December 2028, and to extend the deadlines for the adoption of certain harmonised standards to 27 May 2028.

(14) The intention to request revision of existing standards and development of new standards in support of Regulations (EU) 2017/745 and (EU) 2017/746 is stated in point 70 of the Annex to the 2023 annual Union work programme for European standardisation[9].

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

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

(17) Due to the large number of amendments in Annexes I and II to Implementing Decision C(2021) 2406, those Annexes should, in the interest of legal clarity and rationality, be replaced.

[9] C(2023) 1210 final of 27 February 2023 (OJ C 93, 13.3.2023, p. 2).

(18) The implementation of the request by CEN and CENELEC demonstrated the key role of Annex Z to harmonised standards to deal with differences in definitions of terms in a harmonised standard with respect to those set out in Regulation (EU) 2017/745 or (EU) 2017/746, and with normative references to undated standards.

(19) The requirements for certain specific standards listed in Annexes I and II to the request include references to dated standards that may limit the extent of the standardisation work to be carried out by CEN and CENELEC. Moreover, for standard EN ISO 15223-1, it is necessary to include an explicit requirement on the symbol for the authorised representative in the Union, to ensure full coherence with current terminology.

(20) It is therefore appropriate to modify certain general requirements and the requirements for certain specific standards.

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

(22) 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.

(23) 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 lay down rules on the applicability of this Decision in the event that CEN or CENELEC does not accept the amendments to Implementing Decision C(2021) 2406 set out in this Decision.

(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

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

(1) in Article 3, paragraph 3 is replaced by the following:

'3. CEN and CENELEC shall provide the Commission with the joint final report by 30 June 2028.';

(2) in Article 4, the second subparagraph is replaced by the following:

'This Decision shall expire on 31 December 2028.';

(3) Annex I is replaced by the text in Annex I to this Decision;

(4) Annex II is replaced by the text in Annex II to this Decision;

(5) Annex III is amended in accordance with Annex III to this Decision.

Article 2

If the European Committee for Standardization or the European Committee for Electrotechnical Standardization does not accept the amendments set out in Article 1, points (3), (4) and (5), 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, as amended by Implementing Decision C(2023) 694, shall continue to apply to 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, 27.5.2024

For the Commission
Stella KYRIAKIDES
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION