COMMISSION IMPLEMENTING DECISION (EU) 2021/1182

of 16 July 2021

on the harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745 of the European Parliament and of the Council

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(6) thereof,

Whereas:

(1) In accordance with Article 8 of Regulation (EU) 2017/745 of the European Parliament and of the Council ([2]), devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, 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 that Regulation covered by those standards or parts thereof.

(2) Regulation (EU) 2017/745 repealed Council Directives 90/385/EEC ([3]) and 93/42/EEC ([4]) with effect from 26 May 2021.

(3) By Commission Implementing Decision C(2021) 2406 ([5]), 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.

(4) On the basis of the request set out in Implementing Decision C(2021) 2406, CEN revised the existing harmonised standards EN ISO 11135:2014, EN ISO 11137-1:2015, EN ISO 11737-2:2009 and EN ISO 25424:2011, in order to include the latest technical and scientific progress, and to adapt them to the relevant requirements of Regulation (EU) 2017/745. This resulted in the adoption of the new harmonised standards EN ISO 11737-2:2020 and EN ISO 25424:2019, and of the amendments EN ISO 11135:2014/A1:2019 to EN ISO 11135:2014 and EN ISO 11137-1:2015/A2:2019 to EN ISO 11137-1:2015.

(5) On the basis of the request set out in the Implementing Decision C(2021) 2406, CEN drafted the new harmonised standard EN ISO 10993-23:2021.

(6) The Commission together with CEN has assessed whether the standards revised and drafted by CEN comply with the request set out in Implementing Decision C(2021) 2406.

([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]) Commission 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.

(7) The harmonised standards EN ISO 10993-23:2021, EN ISO 11737-2:2020 and EN ISO 25424:2019 and the amendments EN ISO 11135:2014/A1:2019 to EN ISO 11135:2014 and EN ISO 11137-1:2015/A2:2019 to EN ISO 11137-1:2015 satisfy the requirements which they aim to cover and which are set out in Regulation (EU) 2017/745. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.

(8) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The references of harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745 and listed in the Annex to this Decision are hereby published in the *Official Journal of the European Union*.

Article 2

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 16 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

No	Reference of the standard
1.	EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
2.	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 (ISO 11135:2014) EN ISO 11135:2014/A1:2019
3.	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 (ISO 11137-1:2006, including Amd 1:2013) EN ISO 11137-1:2015/A2:2019
4.	EN ISO 11737-2:2020 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
5.	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 (ISO 25424:2018)