EU DECLARATION OF CONFORMITY

OFFICIAL JOURNAL OF MEDICAL DEVICES REGULATION (EU) 2017/745

EU DECLARATION OF CONFORMITY

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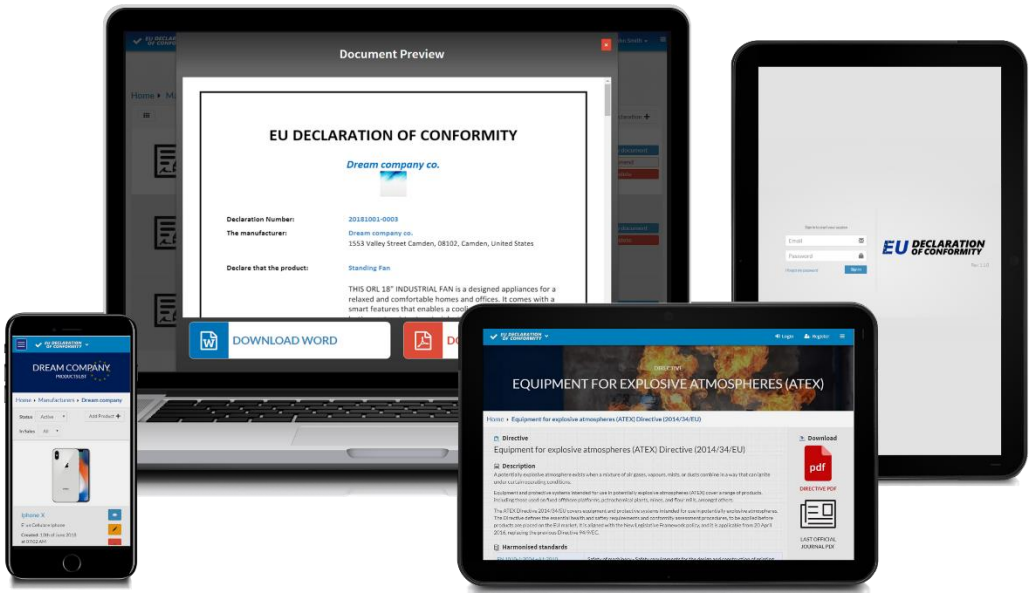

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2022/6

of 4 January 2022

amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for biological evaluation of medical devices, sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by the manufacturer, processing of health care products and home light therapy equipment

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(1) 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 replaced Council Directives 90/385/EEC [3] and 93/42/EEC [4] from 26 May 2021.

(3) By 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 and Cenelec revised the harmonised standards EN ISO 10993-9:2009, EN ISO 10993-12:2012, EN ISO 11737-1:2018, EN ISO 13408-6:2011, EN ISO 13485:2016, EN ISO 14160:2011, EN ISO 15223-1:2016, EN ISO 17664:2017 and EN IEC 60601-2-83:2020, in order to take into account the latest technical and scientific progress and to adapt them to the requirements of Regulation (EU) 2017/745. This resulted in the adoption of the revised harmonised standards EN ISO 10993-9:2021 and EN ISO 10993-12:2021 on biological evaluation of medical devices, EN ISO 13408-6:2021 on aseptic processing of health care products, EN ISO 14160:2021 on sterilization of health care products, EN ISO 15223-1:2021 on symbols to be used with information to be supplied by the manufacturer 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] 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 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.

EN ISO 17664-1:2021 on processing of health care products and of amendment EN ISO 11737-1:2018/A1:2021 to harmonised standard EN ISO 11737-1:2018 on sterilization of health care products, amendment EN ISO 13485:2016/A11:2021 to harmonised standard EN ISO 13485:2016 on quality management systems and amendment EN IEC 60601-2-83:2020/A11:2021 to harmonised standard EN IEC 60601-2-83:2020 on particular requirements for the basic safety and essential performance of home light therapy equipment.

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

(6) The harmonised standards EN ISO 10993-9:2021, EN ISO 10993-12:2021, EN ISO 13408-6:2021, EN ISO 14160:2021, EN ISO 15223-1:2021 and EN ISO 17664-1:2021 and the amendments EN ISO 11737-1:2018/A1:2021, EN ISO 13485:2016/A11:2021 and EN IEC 60601-2-83:2020/A11:2021 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*.

(7) The Annex to Commission Implementing Decision (EU) 2021/1182 ([6]) lists the references of harmonised standards drafted in support of Regulation (EU) 2017/745. In order to ensure that the references of harmonised standards drafted in support of Regulation (EU) 2017/745 are listed in one act, the references of standards EN ISO 10993-9:2021, EN ISO 10993-12:2021, EN ISO 13408-6:2021, EN ISO 14160:2021, EN ISO 15223-1:2021 and EN ISO 17664-1:2021 and the amendments EN ISO 11737-1:2018/A1:2021, EN ISO 13485:2016/A11:2021 and EN IEC 60601-2-83:2020/A11:2021 should be included in that Implementing Decision.

(8) Implementing Decision (EU) 2021/1182 should therefore be amended accordingly.

(9) 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 Annex to Implementing Decision (EU) 2021/1182 is amended in accordance with the Annex to this Decision.

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, 4 January 2022.

For the Commission
The President
Ursula VON DER LEYEN

([6]) 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 (OJ L 256, 19.7.2021, p. 100).

ANNEX

In the Annex to Implementing Decision (EU) 2021/1182, the following entries are added:

No	Reference of the standard
‘6.	EN ISO 10993-9:2021 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2019)
7.	EN ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
8.	EN ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018) EN ISO 11737-1:2018/A1:2021
9.	EN ISO 13408-6:2021 Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2021)
10.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/A11:2021
11.	EN ISO 14160:2021 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 (ISO 14160:2020)
12.	EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)
13.	EN ISO 17664-1:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices (ISO 17664-1:2021)
14.	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 EN IEC 60601-2-83:2020/A11:2021’.