EU DECLARATION OF CONFORMITY

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

EU DECLARATION OF CONFORMITY

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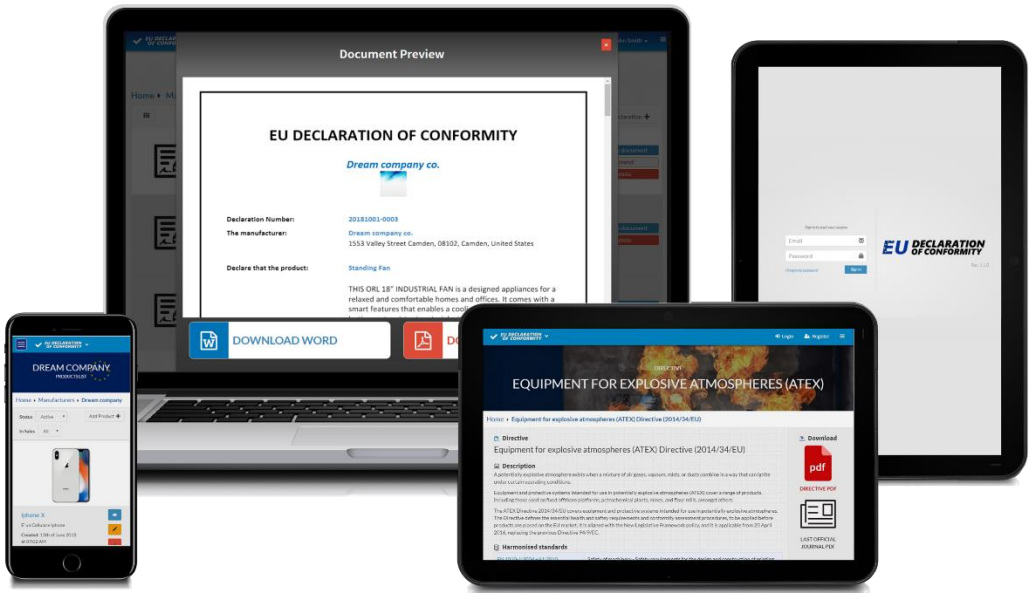

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COMMISSION IMPLEMENTING DECISION (EU) 2024/815

of 6 March 2024

amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for medical gloves for single use, biological evaluation of medical devices, sterilization of health care products, packaging for terminally sterilized medical devices and processing of health care products

(Text with EEA relevance)

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]) with effect 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 for the drafting of new harmonised standards in support of Regulation (EU) 2017/745 ('the request').

(4) On the basis of the request, CEN and Cenelec revised the harmonised standards EN 455-3:2015 on medical gloves for single use, EN ISO 10993-15:2009 on biological evaluation of medical devices, EN ISO 10993-17:2009 on biological evaluation of medical devices, EN ISO 10993-18:2020 on biological evaluation of medical devices, EN ISO 11137-2:2015 on sterilization of health care products, EN ISO 11607-1:2020 on packaging for terminally sterilized medical devices, EN ISO 11607-2:2020 on packaging for terminally sterilized medical devices, and EN ISO 17664:2017 on processing of health care products, the references of which are not published in the *Official Journal of the European Union*, in order to take into account the latest technical and scientific progress and the need to

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

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

([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]) 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.

support the requirements of Regulation (EU) 2017/745. This resulted in the adoption of harmonised standards EN 455-3:2023, EN ISO 10993-15:2023, EN ISO 10993-17:2023 and EN ISO 17664-2:2023 (the 'standards'), and of the amendments EN ISO 10993-18:2020/A1:2023, EN ISO 11137-2:2015/A1:2023, EN ISO 11607-1:2020/A1:2023 and EN ISO 11607-2:2020/A1:2023 (the 'amendments').

(5) The Commission together with CEN and Cenelec has assessed whether the standards and the amendments comply with the request.

(6) The standards and the amendments 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 the standards and of the amendments 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.

(8) 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 the standards and of the amendments should be included in Implementing Decision (EU) 2021/1182.

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

(10) 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 day 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, 6 March 2024.

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, ELI: http://data.europa.eu/eli/dec_impl/2021/1182/oj).

ANNEX

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

No	Reference of the standard
'18.	EN 455-3:2023 Medical gloves for single use – Part 3: Requirements and testing for biological evaluation
19.	EN ISO 10993-15:2023 Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2019)
20.	EN ISO 10993-17:2023 Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents (ISO 10993-17:2023)
21.	EN ISO 10993-18:2020 Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020) EN ISO 10993-18:2020/A1:2023
22.	EN ISO 11137-2:2015 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose (ISO 11137-2:2013) EN ISO 11137-2:2015/A1:2023
23.	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019) EN ISO 11607-1:2020/A1:2023
24.	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019) EN ISO 11607-2:2020/A1:2023
25.	EN ISO 17664-2:2023 Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 2: Non-critical medical devices (ISO 17664-2:2021)'.