COMMISSION IMPLEMENTING DECISION (EU) 2021/610

of 14 April 2021

amending Implementing Decision (EU) 2020/437 as regards harmonised standards on medical vehicles and their equipment, anaesthetic and respiratory equipment, biological evaluation of medical devices, packaging for terminally sterilised medical devices, sterilisation of health care products, clinical investigation of medical devices for human subjects, non-active surgical implants, medical devices utilising animal tissues and their derivatives, electroacoustics and medical electrical 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 5(1) of Council Directive 93/42/EEC ([2]), Member States are to presume compliance with the essential requirements referred to in Article 3 of that Directive in respect of medical devices which are in conformity with the relevant national standards adopted pursuant to the harmonised standards the references of which have been published in the *Official Journal of the European Union*.

(2) By letters BC/CEN/CENELEC/09/89 of 19 December 1991, M/023 - BC/CEN/03/023/93-08 of 5 August 1993, M/295 of 9 September 1999, M/320 of 13 June 2002 and M/432 of 24 November 2008, the Commission made requests to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) for the drafting of new harmonised standards and the revision of existing harmonised standards in support of Directive 93/42/EEC.

(3) On the basis of request M/023 - BC/CEN/03/023/93-08, CEN revised the harmonised standards EN 1789:2007 +A1:2010, EN ISO 10993-16:2010, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-2:2009, EN 13718-1:2008, EN 13718-2:2015, EN ISO 22442-1:2007 and EN ISO 22442-2:2007, the references of which have been published by Commission Implementing Decision (EU) 2020/437 ([3]). That revision resulted in the adoption of the harmonised standards EN 1789:2020 on medical vehicles and their equipment, EN ISO 10993-16:2017 on biological evaluation of medical devices, EN ISO 11607-1:2020 and EN ISO 11607-2:2020 on packaging for terminally sterilised medical devices, EN ISO 11737-2:2020 on sterilisation of health care products, EN 13718-1:2014+A1:2020 and EN 13718-2:2015+A1:2020 on medical vehicles and their equipment and finally EN ISO 22442-1:2020 and EN ISO 22442-2:2020 on medical devices utilising animal tissues and their derivatives.

(4) On the basis of request BC/CEN/CENELEC/09/89, CEN revised the harmonised standard EN ISO 10993-18:2009, the reference of which has been published by Implementing Decision (EU) 2020/437. That revision resulted in the adoption of the harmonised standard EN ISO 10993-18:2020 on biological evaluation of medical devices.

(5) On the basis of request M/295, CEN and Cenelec revised the harmonised standards EN ISO 14155:2011 as corrected by EN ISO 14155:2011/AC:2011, and EN 60601-2-4:2003, the references of which have been published by Implementing Decision (EU) 2020/437. That revision resulted in the adoption of the harmonised standards EN ISO 14155:2020 on clinical investigation of medical devices for human subjects and EN 60601-2-4:2011 on medical electrical equipment.

([1]) OJ L 316, 14.11.2012, p. 12.
([2]) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).
([3]) Commission Implementing Decision (EU) 2020/437 of 24 March 2020 on the harmonised standards for medical devices drafted in support of Council Directive 93/42/EEC (OJ L 90 I, 25.3.2020, p. 1).

(6) On the basis of requests M/320 and M/023 - BC/CEN/03/023/93-08, CEN revised the harmonised standard EN ISO 14607:2009, the reference of which has been published by Implementing Decision (EU) 2020/437. That revision resulted in the adoption of the harmonised standard EN ISO 14607:2018 on non-active surgical implants.

(7) On the basis of requests M/432 and M/023 - BC/CEN/03/023/93-08, Cenelec revised the harmonised standard EN 60118-13:2005, the reference of which has been published by Implementing Decision (EU) 2020/437. That revision resulted in the adoption of the harmonised standard EN IEC 60118-13:2020 on electroacoustics.

(8) On the basis of request M/023 - BC/CEN/03/023/93-08, CEN and Cenelec drafted the harmonised standard EN ISO 5361:2016 on anaesthetic and respiratory equipment and the harmonised standards EN IEC 60601-2-83:2020 and EN ISO 80601-2-55:2018 on medical electrical equipment.

(9) On the basis of requests M/432 and M/023 - BC/CEN/03/023/93-08, Cenelec drafted the harmonised standard EN IEC 60601-2-66:2020 on medical electrical equipment.

(10) The Commission together with CEN and Cenelec has assessed whether the harmonised standards drafted and revised by CEN and Cenelec comply with the relevant requests.

(11) The harmonised standards EN 1789:2020, EN ISO 5361:2016, EN ISO 10993-16:2017, EN ISO 10993-18:2020, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-2:2020, EN 13718-1:2014+A1:2020, EN 13718-2:2015+A1:2020, EN ISO 14155:2020, EN ISO 14607:2018, EN ISO 22442-1:2020, EN ISO 22442-2:2020, EN IEC 60118-13:2020, EN 60601-2-4:2011, EN IEC 60601-2-66:2020, EN IEC 60601-2-83:2020 and EN ISO 80601-2-55:2018 satisfy the requirements which they aim to cover and which are set out in Directive 93/42/EEC. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.

(12) It is necessary to replace the references of harmonised standards EN 1789:2007+A1:2010, EN ISO 10993-16:2010, EN ISO 10993-18:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-2:2009, EN 13718-1:2008, EN 13718-2:2015, EN ISO 14155:2011 as corrected by EN ISO 14155:2011/AC:2011, EN ISO 14607:2009, EN ISO 22442-1:2007, EN ISO 22442-2:2007, EN 60118-13:2005 and EN 60601-2-4:2003, published by Implementing Decision (EU) 2020/437, as those standards have been revised.

(13) Annex I to Implementing Decision (EU) 2020/437 lists the references of harmonised standards drafted in support of Directive 93/42/EEC. In order to ensure that the references of harmonised standards drafted in support of Directive 93/42/EEC are listed in one act, the references of standards EN ISO 5361:2016, EN IEC 60601-2-66:2020, EN IEC 60601-2-83:2020 and EN ISO 80601-2-55:2018 should be included in that Implementing Decision.

(14) Implementing Decision (EU) 2020/437 should therefore be amended accordingly.

(15) 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

Annex I to Implementing Decision (EU) 2020/437 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, 14 April 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex I is amended as follows:

(1) entry 22 is replaced by the following:

No	Reference of the standard
‘22.	EN 1789:2020 Medical vehicles and their equipment - Road ambulances’

(2) entry 81 is replaced by the following:

No	Reference of the standard
‘81.	EN ISO 10993-16:2017 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2017)’

(3) entry 83 is replaced by the following:

No	Reference of the standard
‘83.	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)’

(4) entries 92 and 93 are replaced by the following:

No	Reference of the standard
‘92.	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)
93.	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)’

(5) entry 96 is replaced by the following:

No	Reference of the standard
‘96.	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)’

(6) entries 125 and 126 are replaced by the following:

No	Reference of the standard
‘125.	EN 13718-1:2014+A1:2020 Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances
126.	EN 13718-2:2015+A1:2020 Medical vehicles and their equipment - Air ambulances - Part 2: Operational and technical requirements for air ambulances’

(7) entry 137 is replaced by the following:

No	Reference of the standard
‘137.	EN ISO 14155:2020 Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)’

(8) entry 145 is replaced by the following:

No	Reference of the standard
‘145.	EN ISO 14607:2018 Non-active surgical implants - Mammary implants - Particular requirements (ISO 14607:2018, Corrected version 2018-08)’

(9) entries 180 and 181 are replaced by the following:

No	Reference of the standard
‘180.	EN ISO 22442-1:2020 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management (ISO 22442-1:2020)
181.	EN ISO 22442-2:2020 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2020)’

(10) entry 193 is replaced by the following:

No	Reference of the standard
‘193.	EN IEC 60118-13:2020 Electroacoustics - Hearing aids - Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices’

(11) entry 208 is replaced by the following:

No	Reference of the standard
‘208.	EN 60601-2-4:2011 Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators’

(12) the following entries 265 to 268 are added:

No	Reference of the standard
‘265.	EN ISO 5361:2016 Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO 5361:2016)
266.	EN IEC 60601-2-66:2020 Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems (IEC 60601-2-66:2019)
267.	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
268.	EN ISO 80601-2-55:2018 Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2018)’