EU DECLARATION OF CONFORMITY

OFFICIAL JOURNAL OF ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE (90/385/EEC)

EU DECLARATION OF CONFORMITY

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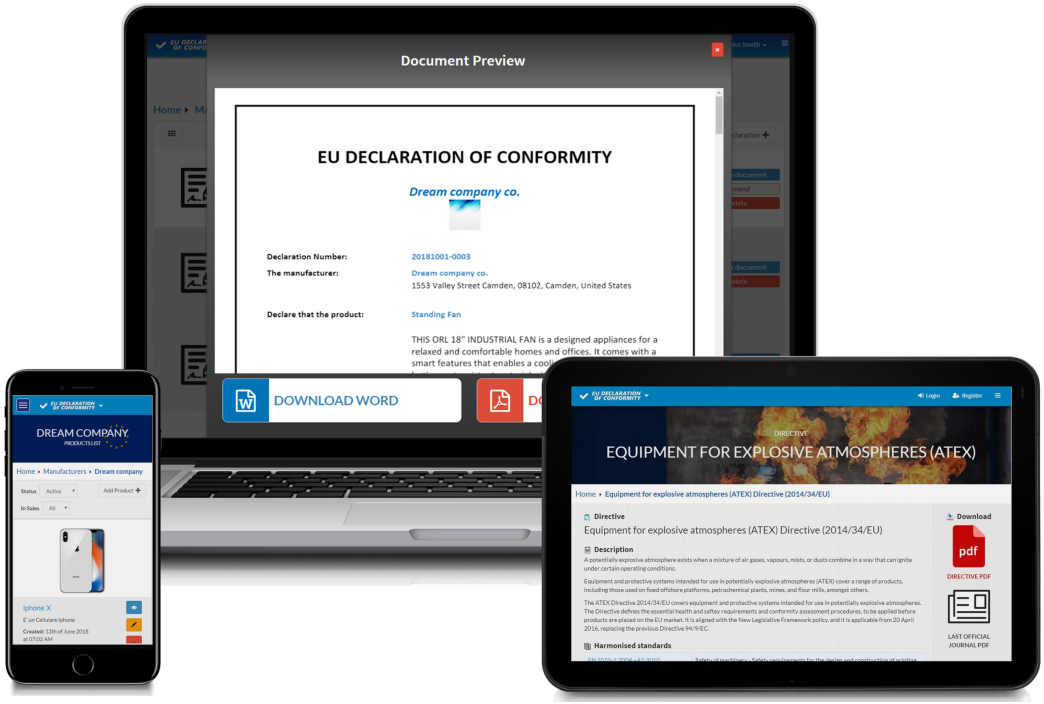

COMMISSION IMPLEMENTING DECISION (EU) 2021/611

of 14 April 2021

amending Implementing Decision (EU) 2020/438 as regards harmonised standards on biological evaluation of medical devices, packaging for terminally sterilised medical devices, sterilisation of health care products and clinical investigation of medical devices for human subjects

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 90/385/EEC ([2]), Member States are to presume compliance with the essential requirements referred to in Article 3 of that Directive in respect of active implantable 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 and M/295 of 9 September 1999, 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 90/385/EEC.

(3) On the basis of request M/023 - BC/CEN/03/023/93-08, CEN revised the harmonised standards EN ISO 10993-16:2010, EN ISO 11607-1:2009 and EN ISO 11737-2:2009, the references of which have been published by Commission Implementing Decision (EU) 2020/438 ([3]). That revision resulted in the adoption of the harmonised standards EN ISO 10993-16:2017 on biological evaluation of medical devices, EN ISO 11607-1:2020 on packaging for terminally sterilised medical devices and EN ISO 11737-2:2020 on sterilisation of health care products.

(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) 2020/438. 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 revised the harmonised standard EN ISO 14155:2011, as corrected by EN ISO 14155:2011/AC:2011, the references of which have been published by Implementing Decision (EU) 2020/438. That revision resulted in the adoption of the harmonised standard EN ISO 14155:2020 on clinical investigation of medical devices for human subjects.

(6) On the basis of request M/023 - BC/CEN/03/023/93-08, CEN drafted the harmonised standard EN ISO 11607-2:2020 on packaging for terminally sterilised medical devices.

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

([1]) OJ L 316, 14.11.2012, p. 12.

([2]) 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).

([3]) Commission Implementing Decision (EU) 2020/438 of 24 March 2020 on the harmonised standards for active implantable medical devices drafted in support of Council Directive 90/385/EEC (OJ L 90 I, 25.3.2020, p. 25).

(8) The harmonised standards 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 and EN ISO 14155:2020 satisfy the requirements which they aim to cover and which are set out in Directive 90/385/EEC. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.

(9) It is necessary to replace the references of harmonised standards EN ISO 10993-16:2010, EN ISO 10993-18:2009, EN ISO 11607-1:2009, EN ISO 11737-2:2009 and EN ISO 14155:2011 as corrected by EN ISO 14155:2011/AC:2011, published by Implementing Decision (EU) 2020/438, as those standards have been revised.

(10) Annex I to Implementing Decision (EU) 2020/438 lists the references of harmonised standards drafted in support of Directive 90/385/EEC. In order to ensure that the references of harmonised standards drafted in support of Directive 90/385/EEC are listed in one act, the reference of standard EN ISO 11607-2:2020 should be included in that Implementing Decision.

(11) Implementing Decision (EU) 2020/438 should therefore be amended accordingly.

(12) 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) 2020/438 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 14 is replaced by the following:

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

(2) entry 16 is replaced by the following:

No	Reference of the standard
‘16.	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)’

(3) entry 23 is replaced by the following:

No	Reference of the standard
‘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)’

(4) entry 25 is replaced by the following:

No	Reference of the standard
‘25.	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) entry 34 is replaced by the following:

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

(6) the following entry 47 is added:

No	Reference of the standard
‘47.	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)’