EU DECLARATION OF CONFORMITY

OFFICIAL JOURNAL OF IN VITRO DIAGNOSTIC MEDICAL DEVICES DIRECTIVE (98/79/EC)

EU DECLARATION OF CONFORMITY

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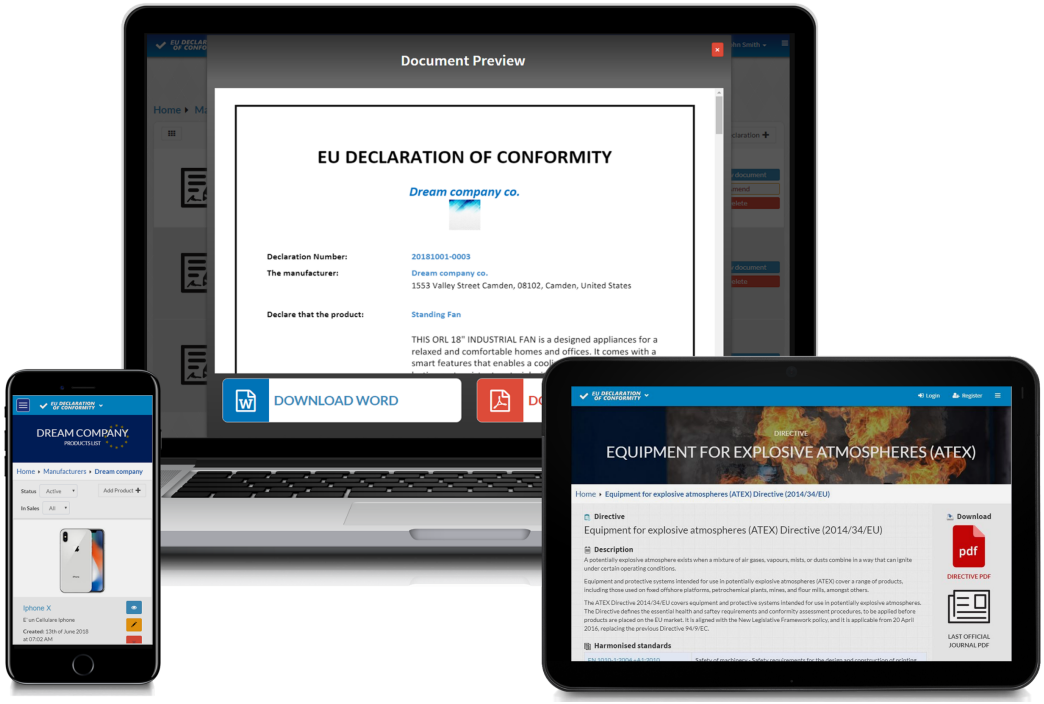

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/609

of 14 April 2021

amending Implementing Decision (EU) 2020/439 as regards harmonised standards on packaging for terminally sterilised medical devices and sterilisation of health care products

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 Directive 98/79/EC of the European Parliament and of the Council [2], Member States are to presume compliance with the essential requirements referred to in Article 3 of that Directive in respect of *in vitro* diagnostic 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 M/023 – BC/CEN/03/023/93-08 of 5 August 1993 and M/252 of 12 September 1997, 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 98/79/EC.

(3) On the basis of request M/252, CEN revised the harmonised standard EN ISO 11737-2:2009, the reference of which has been published by Commission Implementing Decision (EU) 2020/439 [3]. That revision resulted in the adoption of the harmonised standard EN ISO 11737-2:2020 on sterilisation of health care products.

(4) On the basis of request M/023 – BC/CEN/03/023/93-08, CEN drafted the harmonised standards EN ISO 11607-1:2020 and EN ISO 11607-2:2020 on packaging for terminally sterilised medical devices.

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

(6) The harmonised standards EN ISO 11607-1:2020, EN ISO 11607-2:2020 and EN ISO 11737-2:2020 satisfy the requirements which they aim to cover and which are set out in Directive 98/79/EC. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.

(7) It is necessary to replace the reference of harmonised standard EN ISO 11737-2:2009, published by Implementing Decision (EU) 2020/439, as that standard has been revised.

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

[2] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

[3] Commission Implementing Decision (EU) 2020/439 of 24 March 2020 on the harmonised standards for *in vitro* diagnostic medical devices drafted in support of Directive 98/79/EC of the European Parliament and of the Council (OJ L 90 I, 25.3.2020, p. 33).

(8) Annex I to Implementing Decision (EU) 2020/439 lists the references of harmonised standards drafted in support of Directive 98/79/EC. In order to ensure that the references of harmonised standards drafted in support of Directive 98/79/EC are listed in one act, the references of standards EN ISO 11607-1:2020 and EN ISO 11607-2:2020 should be included in that Implementing Decision.

(9) Implementing Decision (EU) 2020/439 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 date of its publication,

HAS ADOPTED THIS DECISION:

Article 1

Annex I to Implementing Decision (EU) 2020/439 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 5 is replaced by the following:

No	Reference of the standard
'5.	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)';

(2) the following entries 42 and 43 are added:

No	Reference of the standard
'42.	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)
43.	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)'.