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

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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 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 the request M/295 of 9 September 1999, CEN revised the harmonised standard EN ISO 10993-11:2009, the reference of which has been published in the *Official Journal of the European Union*[(3)], in order to include the latest technical and scientific progress. This resulted in the adoption of the harmonised standard EN ISO 10993-11:2018.

(4) The Commission together with CEN has assessed whether the harmonised standard EN ISO 10993-11:2018 complies with the request.

(5) The harmonised standard EN ISO 10993-11:2018 satisfies the requirements which it aims to cover and which are set out in Directive 90/385/EEC. It is therefore appropriate to publish the reference of that standard in the *Official Journal of the European Union*.

(6) The harmonised standard EN ISO 10993-11:2018 replaces the harmonised standard EN ISO 10993-11:2009. It is therefore necessary to withdraw the reference of standard EN ISO 10993-11:2009 from the *Official Journal of the European Union*. In order to give manufacturers sufficient time to adapt their products to the revised specifications in standard EN ISO 10993-11:2018, it is necessary to defer the withdrawal of the reference of standard EN ISO 10993-11:2009.

(7) On the basis of the request BC/CEN/CENELEC/09/89 of 19 December 1991, CEN revised the harmonised standards EN ISO 11137-1:2015, EN ISO 13408-2:2011 and EN ISO 13485:2016, the references of which have been published in the *Official Journal of the European Union*[(4)], in order to include the latest technical and scientific progress. This resulted in the adoption of the harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018.

(8) The Commission together with CEN has assessed whether the harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018 comply with the request.

(9) The harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018 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 and of the corrigendum in the *Official Journal of the European Union*.

(10) The harmonised standards EN ISO 11137-1:2015/A2:2019, EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018 replace the harmonised standards EN ISO 11137-1:2015 and EN ISO 13408-2:2011 and the corrigendum EN ISO 13485:2016/AC:2016 respectively. It is therefore necessary to withdraw the references of the harmonised standard EN ISO 11137-1:2015 and EN ISO 13408-2:2011 and of corrigendum EN ISO 13485:2016/AC:2016 from the *Official Journal of the European Union*. In order to give manufacturers sufficient time to adapt their products to the revised specifications in the harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018, it is necessary to defer the withdrawal of the references of harmonised standards EN ISO 11137-1:2015 and EN ISO 13408-2:2011 and of corrigendum EN ISO 13485:2016/AC:2016.

(11) On the basis of the request BC/CEN/CENELEC/09/89 of 19 December 1991, CEN drafted the new harmonised standard EN ISO 25424:2019. The Commission together with CEN has assessed whether that standard complies with the request.

(12) The harmonised standard EN ISO 25424:2019 satisfies the requirements which it aims to cover and which are set out in Directive 90/385/EEC. It is therefore appropriate to publish the reference of that standard in the *Official Journal of the European Union*.

(13) In the interests of clarity and legal certainty, a complete list of references of harmonised standards drafted in support of Directive 90/385/EEC and satisfying the essential requirements they aim to cover should be published in one act. The other references

of standards published in the Commission communication 2017/C 389/02[(5)] should therefore also be included in this Decision. That Communication should therefore be repealed from the date of entry into force of this Decision. However, it should continue to apply in respect of the references of the harmonised standards that are withdrawn by this Decision, given that it is necessary to defer withdrawal of those references.

(14) In accordance with the second subparagraph of Article 120(2) of Regulation (EU) 2017/745 of the European Parliament and of the Council[(6)], certificates issued by notified bodies in accordance with Directive 90/385/EEC from 25 May 2017 are to remain valid until the end of the period indicated on the certificate, which is not to exceed five years from its issuance. They are, however, to become void at the latest on 27 May 2024. In accordance with the first subparagraph of Article 120(3) of Regulation (EU) 2017/745 a device which has a certificate that was issued in accordance with Directive 90/385/EEC and that is valid by virtue of Article 120(2) of Regulation (EU) 2017/745, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2020 it continues to comply with Directive 90/385/EEC, and provided there are no significant changes in the design and intended purpose. This Decision should therefore apply only until 26 May 2024.

(15) The requirements for implantable medical devices laid down in Directive 90/385/EEC are different from those laid down in Regulation (EU) 2017/745. The standards drafted in support of Directive 90/385/EEC should therefore not be used to demonstrate conformity with the requirements of Regulation (EU) 2017/745.

(16) 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 references of the harmonised standards for active implantable medical devices drafted in support of Directive 90/385/EEC and listed in Annex I to this Decision are hereby published in the *Official Journal of the European Union*.

Article 2

Commission communication 2017/C 389/02 is repealed. It shall continue to apply until 30 September 2021 in respect of the references of the harmonised standards listed in Annex II to this Decision.

Article 3

The harmonised standards for active implantable medical devices drafted in support of Directive 90/385/EEC and listed in Annexes I and II to this Decision may not be used to confer presumption of conformity with the requirements of Regulation (EU) 2017/745.

Article 4

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply until 26 May 2024.

Done at Brussels, 24 March 2020.

For the Commission

The President

Ursula VON DER LEYEN

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Decision (EU) 2020/438. (See end of Document for details)*

ANNEX I

No	Reference of the standard
1.	EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices EN 556-1:2001/AC:2006
2.	EN 556-2:2015 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices
3.	EN 1041:2008 Information supplied by the manufacturer of medical devices
4.	EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009) EN ISO 10993-1:2009/AC:2010
5.	EN ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
6.	EN ISO 10993-4:2009 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amd 1:2006)
7.	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
8.	EN ISO 10993-6:2009 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2007)
9.	EN ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008) EN ISO 10993-7:2008/AC:2009
10.	EN ISO 10993-9:2009