EU DECLARATION OF CONFORMITY

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

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COMMISSION IMPLEMENTING DECISION (EU) 2020/438
of 24 March 2020

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,


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.


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.


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.

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 (*) 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.

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.

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.

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
### ANNEX I

<table>
<thead>
<tr>
<th>No</th>
<th>Reference of the standard</th>
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<tbody>
<tr>
<td>2.</td>
<td>EN 556-2:2015&lt;br&gt;Sterilization of medical devices - Requirements for medical devices to be designated &quot;STERILE&quot; - Part 2: Requirements for aseptically processed medical devices</td>
</tr>
<tr>
<td>3.</td>
<td>EN 1041:2008&lt;br&gt;Information supplied by the manufacturer of medical devices</td>
</tr>
<tr>
<td>No</td>
<td>Reference of the standard</td>
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| 17. | EN ISO 11135-1:2007  
| 18. | EN ISO 11137-1:2015  
EN ISO 11137-1:2015/A2:2019 |
| 20. | EN ISO 11138-2:2009  
| 22. | EN ISO 11140-1:2009  
| 23. | EN ISO 11607-1:2009  
| 24. | EN ISO 11737-1:2006  
EN ISO 11737-1:2006/AC:2009 |
| 25. | EN ISO 11737-2:2009  
| 26. | EN ISO 13408-1:2015  
| 27. | EN ISO 13408-2:2018  
| 29. | EN ISO 13408-4:2011  
| 30. | EN ISO 13408-5:2011  
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<tr>
<td>37.</td>
<td>EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)</td>
</tr>
<tr>
<td>40.</td>
<td>EN 45502-1:1997 Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer</td>
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<tr>
<td>41.</td>
<td>EN 45502-2-1:2003 Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.</td>
</tr>
<tr>
<td>42.</td>
<td>EN 45502-2-2:2008 Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators) EN 45502-2-2:2008/AC:2009 Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.</td>
</tr>
<tr>
<td>43.</td>
<td>EN 45502-2-3:2010 Active implantable medical devices - Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.</td>
</tr>
<tr>
<td>No.</td>
<td>Reference of the standard</td>
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</tbody>
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| 44. | EN 60601-1:2006  
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)  
EN 60601-1:2006/AC:2010  
| 45. | EN 60601-1-6:2010  
Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)  
Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC. |
| 46. | EN 62304:2006  
Medical device software - Software life-cycle processes (IEC 62304:2006)  
EN 62304:2006/AC:2008  
Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC. |
## ANNEX II

<table>
<thead>
<tr>
<th>No</th>
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| 1. | EN ISO 10993-11:2009  
| 2. | EN ISO 11137-1:2015  
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)  