COMMISSION IMPLEMENTING DECISION (EU) 2021/1182
of 16 July 2021


THE EUROPEAN COMMISSION,

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


Whereas:

(1) In accordance with Article 8 of Regulation (EU) 2017/745 of the European Parliament and of the Council (²), devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the Official Journal of the European Union, are to be presumed to be in conformity with the requirements of that Regulation covered by those standards or parts thereof.


(3) By Commission Implementing Decision C(2021) 2406 (⁵), the Commission made a request to the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) for the revision of existing harmonised standards on medical devices developed in support of Directives 90/385/EEC and 93/42/EEC and the drafting of new harmonised standards in support of Regulation (EU) 2017/745.


(6) The Commission together with CEN has assessed whether the standards revised and drafted by CEN comply with the request set out in Implementing Decision C(2021) 2406.


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 harmonised standards for medical devices drafted in support of Regulation (EU) 2017/745 and listed in the Annex to this Decision are hereby published in the *Official Journal of the European Union*.

**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, 16 July 2021.

*For the Commission*

*The President*

Ursula VON DER LEYEN
## ANNEX

<table>
<thead>
<tr>
<th>No</th>
<th>Reference of the standard</th>
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| 1. | EN ISO 10993-23:2021  
| 2. | EN ISO 11135:2014  
Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)  
| 3. | EN ISO 11137-1:2015  
EN ISO 11137-1:2015/A2:2019 |
| 4. | EN ISO 11737-2:2020  
| 5. | EN ISO 25424:2019  
Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2018) |