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European foreword

This document (EN 556-2:2024) has been prepared by Technical Committee CEN/TC 204 “Sterilization of medical devices”, the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2025, and conflicting national standards shall be withdrawn at the latest by May 2025.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 556-2:2015.

This document has been prepared under a standardization request M/575 of 14.4.2021 given to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Regulation, see informative Annexes ZA and ZB, which are an integral part of this document.

EN 556, *Sterilization of medical devices — Requirements for medical devices to be designated “STERILE”*, is currently composed with the following parts:

— *Part 1: Requirements for terminally sterilized medical devices*;

— *Part 2: Requirements for aseptically processed medical devices*.

EN 556-2:2024 includes the following significant technical changes with respect to EN 556-2:2015:

- definitions have been aligned with EN ISO 11139;
- the normative references have been updated to the latest editions;
- informative Annex ZA has been replaced with Informative Annexes ZA and ZB giving the relationship with the European Regulations for medical devices and *in vitro* diagnostic medical devices respectively;
- the Bibliography has been updated.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Introduction

Medical devices designated “STERILE” are prepared using appropriate and validated methods. Whenever possible, sterile medical devices are terminally-sterilized using a properly validated and controlled sterilization process (see EN 556-1, EN ISO 11135, EN ISO 11137-1, EN ISO 14160, EN ISO 14937, EN ISO 17665, EN ISO 20857 and EN ISO 25424). When a medical device is intended to be sterile but cannot be terminally sterilized, aseptic processing is the method of manufacture (see EN ISO 13408-1).

Aseptic processing necessitates that either:

a) the entire product is sterilized and then introduced into a sterilized package; or

b) components of the product are sterilized, then further processed/assembled, and the final product packed into a sterilized package.

Processing/assembly and packaging are carried out in a manner that minimizes the opportunity for items to become re-contaminated by carrying out these operations in a controlled environment in which microbial and particulate levels are maintained at or below defined limits and human intervention is minimized.

NOTE EN ISO 15223-1 specifies the label applied to aseptically processed medical devices as

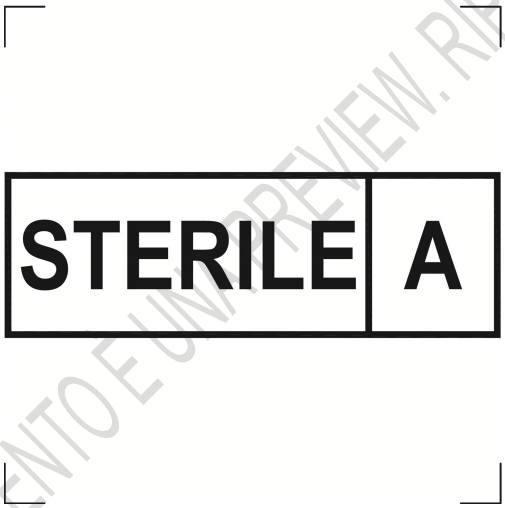

Figure 1

1 Scope

This document specifies the requirements for an aseptically processed medical device to be designated "STERILE".

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 11135:2014,[1] *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices — Amendment 1: Revision of Annex E, Single batch release (ISO 11135:2014)*

EN ISO 11137-1:2015,[2] *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices — Amendment 2: Revision to 4.3.4 and 11.2 (ISO 11137-1:2006)*

EN ISO 13408-2:2018, *Aseptic processing of health care products — Part 2: Sterilizing filtration (ISO 13408-2:2018)*

EN ISO 13408-5:2011, *Aseptic processing of health care products — Part 5: Sterilization in place (ISO 13408-5:2006)*

EN ISO 13485:2016,[3] *Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2016)*

EN ISO 14160:2021, *Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices (ISO 14160:2020)*

EN ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009)*

EN ISO 17665:2024, *Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665:2024)*

EN ISO 20857:2013, *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 20857:2010)*

EN ISO 25424:2019,[4] *Sterilization of medical devices — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2018)*

ISO 22441:2022, *Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

[1] As impacted by EN ISO 11135:2014/A1:2019.

[2] As impacted by EN ISO 11137-1:2015/A2:2019.

[3] As impacted by EN ISO 13485:2016/A11:2021.

[4] As impacted by EN ISO 25424:2019/A1:2022.