



BSI Standards Publication

Sterilization of medical devices — Requirements for medical devices to be designated "STERILE"

Part 2: Requirements for aseptically processed medical devices

This is a preview of BS EN 556-2:2024. [Click here to purchase the full version from the ANSI store.](#)

National foreword

This British Standard is the UK implementation of EN 556-2:2024. It supersedes BS EN 556-2:2015, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

This publication has been prepared under a mandate given to the European Standards Organizations by the European Commission and the European Free Trade Association. It is intended to support requirements of the EU legislation detailed in the European Foreword. A European Annex, usually Annex ZA or ZZ, describes how this publication relates to that EU legislation.

For the Great Britain market (England, Scotland and Wales), if UK Government has designated this publication for conformity with UKCA marking (or similar) legislation, it may contain an additional National Annex. Where such a National Annex exists, it shows the correlation between this publication and the relevant UK legislation. If there is no National Annex of this kind, the relevant Annex ZA or ZZ in the body of the European text will indicate the relationship to UK regulation applicable in Great Britain. References to EU legislation may need to be read in accordance with the UK designation and the applicable UK law. Further information on designated standards can be found at www.bsigroup.com/standardsandregulation.

For the Northern Ireland market, UK law will continue to implement relevant EU law subject to periodic confirmation. Therefore Annex ZA/ZZ in the European text, and references to EU legislation, are still valid for this market.

UK Government is responsible for legislation. For information on legislation and policies relating to that legislation, consult the relevant pages of www.gov.uk.

© The British Standards Institution 2024
Published by BSI Standards Limited 2024

ISBN 978 0 539 22680 5

This is a preview of BS EN 556-2:2024. [Click here to purchase the full version from the ANSI store.](#)

ICS 11.080.01

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2024.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

This is a preview of BS EN 556-2:2024. [Click here to purchase the full version from the ANSI store.](#)

This is a preview of BS EN 556-2:2024. [Click here to purchase the full version from the ANSI store.](#)

EUROPÄISCHE NORM

November 2024

ICS 11.080.01

Supersedes EN 556-2:2015

English Version

Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices

Stérilisation des dispositifs médicaux - Exigences relatives aux dispositifs médicaux en vue d'obtenir l'étiquetage " STÉRILE " - Partie 2 : Exigences relatives aux dispositifs médicaux soumis à un traitement aseptique

Sterilisation von Medizinprodukten - Anforderungen an Medizinprodukte, die als "STERIL" gekennzeichnet werden - Teil 2: Anforderungen an aseptisch hergestellte Medizinprodukte

This European Standard was approved by CEN on 12 August 2024.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

This is a preview of BS EN 556-2:2024. [Click here to purchase the full version from the ANSI store.](#)

Contents	Page
European foreword	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	6
4 Requirements	8
4.1 Validation and routine control	8
4.2 Compliance	11
4.3 Documentation and records	11
Annex ZA (informative) Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered .	12
Annex ZB (informative) Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered .	14
Bibliography	16

This is a preview of BS EN 556-2:2024. [Click here to purchase the full version from the ANSI store.](#)

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.

This is a preview of BS EN 556-2:2024. [Click here to purchase the full version from the ANSI store.](#)

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

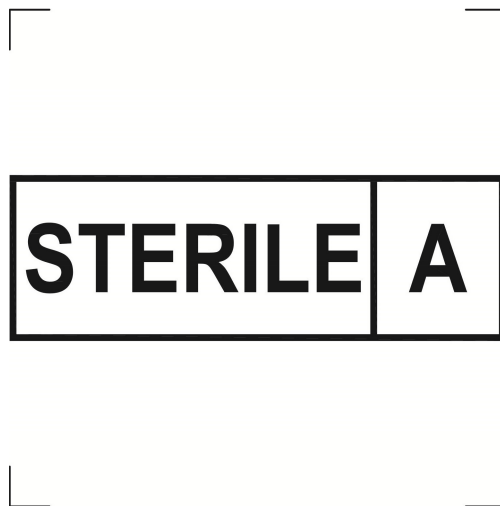


Figure 1

This is a preview of BS EN 556-2:2024. [Click here to purchase the full version from the ANSI store.](#)

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.