



BSI Standards Publication

## Packaging for terminally sterilized medical devices

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Part 1: Requirements for materials, sterile barrier systems and packaging systems

## National foreword

This British Standard is the UK implementation of EN ISO 11607-1:2020. It is identical to ISO 11607-1:2019. It supersedes BS EN ISO 11607-1:2017, which is withdrawn.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 secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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31 March 2020	Implementation of CEN correction notice 12 February 2020: European foreword updated with correct superseding information

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English Version

## Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage (ISO 11607-1:2019)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 1: Anforderungen an Materialien, Sterilbarrieresysteme und Verpackungssysteme (ISO 11607-1:2019)

This European Standard was approved by CEN on 3 November 2018.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 12 February 2020.

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COMITÉ EUROPÉEN DE NORMALISATION  
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**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

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## European foreword

This document (EN ISO 11607-1:2020) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 "Sterilizers and associated equipment for processing of medical devices" the secretariat of which is held by DIN.

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 July 2020, and conflicting national standards shall be withdrawn at the latest by July 2020.

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This document supersedes EN ISO 11607-1:2017.

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## Endorsement notice

The text of ISO 11607-1:2019 has been approved by CEN as EN ISO 11607-1:2020 without any modification.



# INTERNATIONAL STANDARD

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### **Part 1: Requirements for materials, sterile barrier systems and packaging systems**

*Emballages des dispositifs médicaux stérilisés au stade terminal —*

*Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière  
stérile et aux systèmes d'emballage*



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