

Packaging for terminally sterilized medical devices

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

ICS 11.080.30

National foreword

This British Standard is the UK implementation of EN ISO 11607-1:2009+A1:2014. It is identical to ISO 11607-1:2006, incorporating amendment 1:2014. It supersedes BS EN ISO 11607-1:2009 which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization of medical devices.

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

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

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English Version

**Packaging for terminally sterilized medical devices - Part 1:
Requirements for materials, sterile barrier systems and
packaging systems (ISO 11607-1:2006)**

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 11607-1:2006)

Verpackungen für in der Endverpackung zu sterilisierende
Medizinprodukte - Teil 1: Anforderungen an Materialien,
Sterilbarrieresysteme und Verpackungssysteme (ISO
11607-1:2006)

This European Standard was approved by CEN on 16 May 2009.

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 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 Management Centre has the same status as the official versions.

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Foreword

The text of ISO 11607-1:2006 has been prepared by Technical Committee ISO/TC 198 “Sterilization of health care products” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11607-1:2009 by Technical Committee CEN/TC 102 “Sterilizers for medical purposes” 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 December 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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This document supersedes EN ISO 11607-1:2006.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

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

Endorsement notice

The text of ISO 11607-1:2006 has been approved by CEN as a EN ISO 11607-1:2009 without any modification.

Foreword to amendment A1

This document (EN ISO 11607-1:2009/A1:2014) has been prepared by Technical Committee ISO/TC 198 “Sterilization of health care products” in collaboration with Technical Committee CEN/TC 102 “Sterilizers for medical purposes” the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 11607-1:2009 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2015, and conflicting national standards shall be withdrawn at the latest by January 2015.

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For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 11607-1:2006/Amd 1:2014 has been approved by CEN as EN ISO 11607-1:2009/A1:2014 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this International Standard and Directive 93/42/EEC on medical devices

Clause(s)/subclause(s) of this International standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/notes
5.1.3, 5.1.4, 5.1.5, 5.5	7.2	
5.1.6 e), 5.1.7 a), 5.1.7 d), 5.1.7 f), 5.1.7 g), 5.1.9 a), 5.3.1, 6.1.3, 6.2.3,	7.3, 1st part	
5.1.7 a), 5.1.7 g), 5.1.9 a), 5.4 c)	7.5, 1st paragraph	
5.1.7 g)	7.5, 2nd paragraph	Partly addressed. Only toxics are dealt with.
5.1.6 a), 5.1.10 b) 5.1.10 c), 5.2, 6.1.1, 6.1.2, 6.1.4	7.6	Partly addressed. To fully address the ER, validation requirements for forming, sealing and assembling processes need to be addressed (ISO 11607-2).
5.1.6 a), 5.1.10 b), 5.1.10 c), 5.2, 6.1.1, 6.1.2, 6.1.4, 6.2.2, 6.3.5	8.1	Partly addressed. To fully address the ER, validation requirements for forming, sealing and assembling processes need to be addressed (ISO 11607-2).
5.1.10 a), 5.1.10 b), 5.1.10 c), 6.1.1, 6.1.2, 6.1.4, 6.2.2, 6.3.1, 6.3.5, 6.4.1, 7.1	8.3	Partly addressed. To fully address the ER, validation requirements for forming, sealing and assembling processes need to be addressed (ISO 11607-2).
5.1.3, 5.1.4, 5.1.5, 5.1.7 d)	8.5	

5.1.3, 5.1.4, 5.1.5, 7.1, 5.1.6 e), 5.1.7 f), 5.1.7 g), 5.1.9 a), 5.3, 6.1.3	8.6	
5.3.6, 7.1	9.1	Partly addressed. To fully address the ER, validation requirements for forming, sealing and assembling processes need to be addressed (ISO 11607-2).
6.2.3 h), 6.2.3 j), 7.1	9.2, 2nd dash	Partly addressed. Standard does not mention or define values and/or limits.
7	13.1	Partly addressed. Training and knowledge of the potential users is not dealt with.
7	13.3 a), b), d), e), f), i), j), m)	
5.1.10 d), 5.1.11 b), 5.1.12	13.6 h)	Partly addressed. Standard requires this information only for reusable SBS.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 11607-1 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO 11607-1 and ISO 11607-2 cancel and replace ISO 11607:2003, which has been technically revised.

ISO 11607 consists of the following parts, under the general title *Packaging for terminally sterilized medical devices*:

- *Part 1: Requirements for materials, sterile barrier systems and packaging systems*
- *Part 2: Validation requirements for forming, sealing and assembly processes*

Introduction

The process of designing and developing a packaging system for terminally sterilized medical devices is a complicated and critical endeavour. The device components and the packaging system should be combined to create a product that performs efficiently, safely, and effectively in the hands of the user.

This part of ISO 11607 specifies the basic attributes required of materials and pre-formed systems intended for use in packaging systems for terminally sterilized medical devices, while considering the wide range of potential materials, medical devices, packaging system designs, and sterilization methods. ISO 11607-2 describes the validation requirements for forming, sealing and assembly processes. ^[A1] This part of ISO 11607 replaces EN 868-1 ^[A1] and specifies general requirements for all packaging materials whereas EN 868 Parts 2 to 10 specify particular requirements for a range of commonly used materials. Both parts of ISO 11607 were designed to meet the Essential Requirements of the European Medical Device Directives.

European standards that provide requirements for particular materials and preformed sterile barrier systems are available and known as the EN 868 series. This part of ISO 11607 has been developed as a means to show compliance with the relevant Essential Requirements of the European Directives concerning medical devices. Compliance with EN 868 Parts 2 to 10 can be used to demonstrate compliance with one or more of the requirements of this part of ISO 11607.

The goal of a terminally sterilized medical device packaging system is to allow sterilization, provide physical protection, maintain sterility up to the point of use and allow aseptic presentation. The specific nature of the medical device, the intended sterilization methods(s), the intended use, expiry date, transport and storage all influence the packaging system design and choice of materials.

One significant barrier to harmonization was terminology. The terms “package”, “final package”, “final pack”, “primary pack”, and “primary package” all have different connotations around the globe, and choosing one of these terms to be the harmonized basis for this part of ISO 11607 was considered a barrier to successful completion of this document. As a result, the term “sterile barrier system” was introduced to describe the minimum packaging required to perform the unique functions required of medical packaging: to allow sterilization, to provide an acceptable microbial barrier, and to allow for aseptic presentation. “Protective packaging” protects the sterile barrier system, and together they form the packaging system. “Preformed sterile barrier systems” would include any partially assembled sterile barrier systems such as pouches, header bags or hospital packaging reels. An overview of sterile barrier systems can be found in Annex A.

The sterile barrier system is essential to ensure the safety of terminally sterilized medical devices. Regulatory authorities recognize the critical nature of sterile barrier systems by considering them as an accessory or a component of a medical device. Preformed sterile barrier systems sold to healthcare facilities for use in internal sterilization are considered as medical devices in many parts of the world.

Packaging for terminally sterilized medical devices —

Part 1:

Requirements for materials, sterile barrier systems and packaging systems

1 Scope

This part of ISO 11607 specifies the requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use.

This part of ISO 11607 is applicable to industry, to health care facilities, and wherever medical devices are placed in sterile barrier systems and sterilized.

This part of ISO 11607 does not cover all requirements for sterile barrier systems and packaging systems for medical devices that are manufactured aseptically. Additional requirements might also be necessary for drug/device combinations.

This part of ISO 11607 does not describe a quality assurance system for control of all stages of manufacture.

A1 This part of ISO 11607 does not apply to packaging materials and/or systems used to contain a contaminated medical device during transportation of the item to the site of reprocessing or disposal. **A1**

2 Normative references

The following referenced documents are indispensable for the application 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.

ISO 5636-5 **A1** *Text deleted A1*, Paper and board — Determination of air permeance and air resistance (medium range) — Part 5: Gurley method

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

aseptic presentation

introduction and transfer of a sterile product using conditions and procedures that exclude microbial contamination

3.2

bioburden

population of viable microorganisms on or in a product or sterile barrier system

[ISO/TS 11139:2006]

3.3

closure

means used to close a sterile barrier system where no seal is formed

NOTE For example, a sterile barrier system can be closed by a reusable container gasket or sequential folding to construct a tortuous path.

3.4

closure integrity

[A1] characteristics of the closure which ensure that it prevents the ingress of microorganisms, demonstrated under test conditions which consider sterilization process, handling, distribution, transport and storage **[A1]**

3.5

expiry date

indication of the date, by which the product should be used, expressed at least as the year and month

3.6

labelling

written, printed, electronic or graphic matter affixed to a medical device or its packaging system; or accompanying a medical device

NOTE Labelling is related to identification, technical description and use of the medical device but excludes shipping documents.

3.7

medical device

any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical purposes by means of in vitro examination of specimens derived from the human body;

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

[ISO 13485:2003]

NOTE This definition from ISO 13485:2003 has been developed by the Global Harmonization Task Force (GHTF 2002).

3.8

microbial barrier

[A1] property of the sterile barrier system which ensures that it prevents the ingress of microorganisms, demonstrated under test conditions which consider sterilization process, handling, distribution, transport and storage **[A1]**

3.9

packaging material

any material used in the fabrication or sealing of a packaging system