

**Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes**

Packaging for terminally sterilized medical devices -  
Part 2: Validation requirements for forming, sealing  
and assembly processes

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 11607-2:2006 sisaldab Euroopa standardi EN ISO 11607-2:2006 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 29.05.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 11607-2:2006 consists of the English text of the European standard EN ISO 11607-2:2006.</p> <p>This document is endorsed on 29.05.2006 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
--	---

<p><b>Käsitlusala:</b></p> <p>This part of ISO 11607 specifies the requirements for development and validation of processes for packaging medical devices that are terminally sterilized. These processes include forming, sealing, and assembly of preformed sterile barrier systems, sterile barrier systems and packaging systems.</p>	<p><b>Scope:</b></p> <p>This part of ISO 11607 specifies the requirements for development and validation of processes for packaging medical devices that are terminally sterilized. These processes include forming, sealing, and assembly of preformed sterile barrier systems, sterile barrier systems and packaging systems.</p>
---	---

**ICS** 11.080.30

**Võtmesõnad:**

English Version

**Packaging for terminally sterilized medical devices - Part 2:  
Validation requirements for forming, sealing and assembly  
processes (ISO 11607-2:2006)**

Emballages des dispositifs médicaux stérilisés au stade  
terminal - Partie 2: Exigences de validation pour les  
procédés de formage, scellage et assemblage (ISO 11607-  
2:2006)

Verpackungen für in der Endverpackung zu sterilisierende  
Medizinprodukte - Teil 2: Validierungsanforderungen an  
Prozesse der Formgebung, Siegelung und des  
Zusammenstellens (ISO 11607-2:2006)

This European Standard was approved by CEN on 13 April 2006.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, 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 United Kingdom.



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

**Management Centre: rue de Stassart, 36 B-1050 Brussels**

## Foreword

This document (EN ISO 11607-2:2006) 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 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 October 2006, and conflicting national standards shall be withdrawn at the latest by October 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 EU Directive(s).

For relationship with EU Directive(s), 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, 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 United Kingdom.

## Endorsement notice

The text of ISO 11607-2:2006 has been approved by CEN as EN ISO 11607-2:2006 without any modifications.

## ANNEX ZA

(informative)

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

This International 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 Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative 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)/Sub-clause(s) of this International Standard	Essential Requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4.1	1, 2	
4.2, 4.3, 4.4	3, 4, 5, 6	
5.1 to 5.7	7.1, 7.5, 7.6, 8.1, 8.5	
6.1	8.5	
6.3	8.6	
7	1,2, 6, 8.5, 8.6	
8.1, 8.2	7.1, 7.5, 7.6, 8.1	

**WARNING:** Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

---

---

**Packaging for terminally sterilized  
medical devices —**

**Part 2:  
Validation requirements for forming,  
sealing and assembly processes**

*Emballages des dispositifs médicaux stérilisés au stade terminal —*

*Partie 2: Exigences de validation pour les procédés de formage,  
scellage et assemblage*



**PDF disclaimer**

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2006

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 General requirements</b> .....	<b>4</b>
4.1 Quality systems .....	4
4.2 Sampling.....	4
4.3 Test methods.....	4
4.4 Documentation.....	5
<b>5 Validation of packaging processes</b> .....	<b>5</b>
5.1 General.....	5
5.2 Installation qualification (IQ) .....	6
5.3 Operational qualification (OQ).....	6
5.4 Performance qualification (PQ).....	7
5.5 Formal approval of the process validation .....	8
5.6 Process control and monitoring .....	8
5.7 Process changes and revalidation.....	8
<b>6 Packaging system assembly</b> .....	<b>8</b>
<b>7 Use of reusable sterile barrier systems</b> .....	<b>9</b>
<b>8 Sterile fluid-path packaging</b> .....	<b>9</b>
<b>Annex A (informative) Process development</b> .....	<b>10</b>
<b>Bibliography</b> .....	<b>11</b>



## 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 11607-2 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

Medical devices delivered in a sterile state should be designed, manufactured and packed to ensure that they are sterile when placed on the market and remain sterile, under documented storage and transport conditions, until the sterile barrier system is damaged or opened. Additionally, medical devices delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.

One of the most critical characteristics of a sterile barrier system and packaging system for sterile medical devices is the assurance of sterility maintenance. The development and validation of packaging processes are crucial to ensure that sterile barrier system integrity is attained and will remain so until opened by the users of sterile medical devices.

There should be a documented process validation program demonstrating the efficacy and reproducibility of all sterilization and packaging processes. Along with the sterilization process, some of the packaging operations that can affect sterile barrier system integrity are forming, sealing, capping or other closure systems, cutting and process handling. This part of ISO 11607 provides the framework of activities and requirements to develop and validate the process used to make and assemble the packaging system. ISO 11607-1 and ISO 11607-2 are designed to meet the Essential Requirements of the European Medical Device Directives.

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.

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 2:

## Validation requirements for forming, sealing and assembly processes

### 1 Scope

This part of ISO 11607 specifies the requirements for development and validation of processes for packaging medical devices that are terminally sterilized. These processes include forming, sealing, and assembly of preformed sterile barrier systems, sterile barrier systems and packaging systems.

This part of ISO 11607 is applicable to industry, to health care facilities, and wherever medical devices are packaged and sterilized.

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

### 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 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

### 3 Terms and definitions

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

#### 3.1

##### **expiry date**

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

#### 3.2

##### **installation qualification**

##### **IQ**

process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

[ISO/TS 11139:2006]