

# Packaging for terminally sterilized medical devices —

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

ICS 11.080.30

# National foreword

This British Standard is the UK implementation of EN ISO 11607-2:2006+A1:2014. It is identical to ISO 11607-2:2006, incorporating amendment 1:2014. It supersedes BS EN ISO 11607-2:2006, which is withdrawn.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.

**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 31 May 2006

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## Amendments/corrigenda issued since publication

| Date              | Comments                                                                              |
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| 30 September 2014 | Implementation of ISO amendment 1:2014 with CEN endorsement A1:2014. Annex ZA amended |
|                   |                                                                                       |
|                   |                                                                                       |
|                   |                                                                                       |

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.

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## **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.

## **Foreword to amendment A1**

This document (EN ISO 11607-2:2006/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 11607:2006 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.

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

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### **Endorsement notice**

The text of ISO 11607-2:2006/Amd 1:2014 has been approved by CEN as EN ISO 11607-2:2006/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 device**

| Clause(s)/subclause(s)<br>of this International<br>standard | Essential<br>Requirements (ERs)<br>of EU Directive<br>93/42/EEC | Qualifying remarks/notes                                                                                                                                    |
|-------------------------------------------------------------|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4.1, 4.3, 5, 6, 7, 8                                        | 7.6                                                             | Partly addressed.<br>To fully address the ER, requirements for materials, sterile barrier systems and packaging systems need to be addressed (ISO 11607-1). |
| 4.1, 4.3, 5, 6, 7, 8                                        | 8.1, 8.3                                                        | Partly addressed.<br>To fully address the ER, requirements for materials, sterile barrier systems and packaging systems need to be addressed (ISO 11607-1). |
| 5                                                           | 8.4                                                             |                                                                                                                                                             |
| 6.1                                                         | 8.5                                                             | Partly addressed.<br>Standard does not mention or define values and/or limits.                                                                              |
| 6.3                                                         | 8.6, 2nd part                                                   | Partly addressed.<br>To fully address the ER, requirements for materials, sterile barrier systems and packaging systems need to be addressed (ISO 11607-1). |

## Contents

Page

|                                                     |    |
|-----------------------------------------------------|----|
| Foreword .....                                      | v  |
| Introduction .....                                  | vi |
| 1 Scope .....                                       | 1  |
| 2 Normative references .....                        | 1  |
| 3 Terms and definitions.....                        | 1  |
| 4 General requirements.....                         | 4  |
| 4.1 Quality systems .....                           | 4  |
| 4.2 Sampling .....                                  | 4  |
| 4.3 Test methods.....                               | 4  |
| 4.4 Documentation.....                              | 5  |
| 5 Validation of packaging processes.....            | 5  |
| 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  |
| 6 Packaging system assembly .....                   | 8  |
| 7 Use of reusable sterile barrier systems.....      | 9  |
| 8 Sterile fluid-path packaging.....                 | 9  |
| Annex A (informative) Process development .....     | 10 |
| Bibliography .....                                  | 11 |