SLOVENSKI STANDARD

SIST EN ISO 11607-2:2006

01-julij-2006

Embalaģa za konļno sterilizirane medicinske pripomoļke - 2. del: Zahteve validacije za proces oblikovanja, oznaļevanja in sestavljanja (ISO 11607-2:2006)

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

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)

Ta slovenski standard je istoveten z: **EN ISO 11607-2:2006**

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11.080.30

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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 11607-2

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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

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Ref. No. EN ISO 11607-2:2006: E

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.

INTERNATIONAL STANDARD

ISO 11607-2

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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

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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 11607-2 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.