Norma Española

UNE-CEN ISO/TS 16775:2021

Idioma: Inglés

Envasado para productos sanitarios esterilizados terminalmente. Directrices relativas a la aplicación de las Normas ISO 11607-1 e ISO 11607-2 (ISO/TS 16775:2021) (Ratificada por la Asociación Española de Normalización en enero de 2022.)

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Envasado para productos sanitarios esterilizados terminalmente. Directrices relativas a la aplicación de las Normas ISO 11607-1 e ISO 11607-2 (ISO/TS 16775:2021) (Ratificada por la Asociación Española de Normalización en enero de 2022.)

Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2 (ISO/TS 16775:2021) (Endorsed by Asociación Española de Normalización in January of 2022.)

Emballages des dispositifs médicaux stérilisés au stade terminal - Lignes directrices relatives à l'application de l'ISO 11607-1 et l'ISO 11607-2 (ISO/TS 16775:2021) (Entérinée par l'Asociación Española de Normalización en janvier 2022.)

En cumplimiento del punto 11.2.5.4 de las Reglas Internas de CEN/CENELEC Parte 2, se ha otorgado el rango de documento normativo español UNE al documento normativo europeo CEN ISO/TS 16775:2021 (Fecha de disponibilidad 2021-11-24)

Este documento está disponible en los idiomas oficiales de CEN/CENELEC/ETSI.

Este anuncio causará efecto a partir del primer día del mes siguiente al de su publicación en la revista UNE.

La correspondiente versión oficial de este documento se encuentra disponible en la Asociación Española de Normalización (Génova 6 28004 MADRID, www.une.org).

Las observaciones a este documento han de dirigirse a:

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TECHNICAL SPECIFICATION
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English Version

Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2 (ISO/TS 16775:2021)

Emballages des dispositifs médicaux stérilisés au stade terminal - Lignes directrices relatives à l'application de l'ISO 11607-1 et l'ISO 11607-2 (ISO/TS 16775:2021)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Leitfaden für die Anwendung von ISO 11607-1 und ISO 11607-2 (ISO/TS 16775:2021)

This Technical Specification (CEN/TS) was approved by CEN on 22 August 2021 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

This document (CEN ISO/TS 16775:2021) 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.

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

This document supersedes CEN ISO/TS 16775:2014.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

In comparison with the previous edition, the following technical modifications have been made:

- clause normative references has been added;
- clause 3 “Terms and definitions” has been updated;
- structural adaptation of the text to the structure of ISO 11607-1:2019 and ISO 11607-2:2019;
- updates to reflect current editions of ISO 11607-1:2019 and ISO 11607-2:2019;
- intent and guidance is provided for each clause of the standard to improve usability of this document;
- new annexes have been added;
- some annexes have been removed.

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

Endorsement notice

The text of ISO/TS 16775:2021 has been approved by CEN as CEN ISO/TS 16775:2021 without any modification.

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers and associated equipment for processing of medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO/TS 16775:2014), which has been technically revised.

The main changes compared to the previous edition are as follows:

— updates to reflect ISO 11607-1:2019 and ISO 11607-2:2019 editions;

— intent and guidance is provided for each clause of the standard to improve usability of this document.

— new annexes have been added;

— some annexes have been removed.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Sterile barrier systems are intended to allow for sterilization, provide physical protection, maintain the sterility of their contents until the point of use and ensure aseptic presentation. The sterile barrier system, depending on conditions of handling, distribution or storage, can be combined with additional protective packaging to create a packaging system.

ISO 11607-1 specifies the requirements for materials, sterile barrier systems, and packaging systems, including the validation of the packaging system design while ISO 11607-2 specifies the requirements for packaging process validation. The requirements outlined in these standards are generic and are applicable to healthcare facilities and wherever medical devices are packaged and sterilized. It is recognized that the circumstances of the application of these standards will be different when they are used in a healthcare facility, by a medical device manufacturer or reprocessor.

This document provides guidance on the application of ISO 11607-1 and ISO 11607-2. This latest revision has been completely reorganised following the structure of ISO 11607-1 and ISO 11607-2 and referring to individual or groups of clauses or subclauses while indicating the intent of the requirements followed by relevant guidance. It can be used for the systematic application of ISO 11607-1 and ISO 11607-2 or as a reference when questions come up about specific requirements. Clause 4 covers the general requirements that are identical in ISO 11607-1 and ISO 11607-2, while Clause 5 applies to ISO 11607-1:2019 and Clause 6 to ISO 11607-2:2019. Guidance on the application of risk management over the packaging life cycle has been added in anticipation of the upcoming amendments to ISO 11607 (all parts).

This guidance document is applicable to healthcare facilities and to industry while differences for the two environments are addressed as necessary. Although healthcare facilities are usually not involved in sterile barrier system design tasks, their part in the sterile barrier system and packaging system design process consists of carefully selecting an appropriate sterile barrier system and protective packaging based on the identified risks related to the content, sterilization method, transport, storage and aseptic presentation. Sterile barrier and packaging systems and the related processes must then be properly validated, and sealing, closure and assembly processes must be controlled and monitored. To ensure patient safety, healthcare facilities should develop written procedures to be implemented by adequately trained personnel. Guidance given in the annexes of this document is applicable to healthcare facilities and/or industry, as indicated.

The conditions of use of this guidance can vary widely around the world and can be subject to interpretation by circumstances and regulatory environments.