Irish Standard
I.S. EN 868-2:2017

Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods

I.S. EN 868-2:2017

Incorporating amendments/corrigenda/National Annexes issued since publication:

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I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

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This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

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National Foreword

I.S. EN 868-2:2017 is the adopted Irish version of the European Document EN 868-2:2017, Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods

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

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 868-2

February 2017

ICS 11.080.30

Supersedes EN 868-2:2009

English Version

Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 2: Enveloppe de stérilisation - Exigences et méthodes d'essai

Verpackungsmaterialien für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 2: Sterilisierverpackung - Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 4 December 2016.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

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

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European foreword

This document (EN 868-2:2017) has been prepared by Technical Committee CEN/TC 102 "Sterilizers and associated equipment for processing of medical devices", 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 August 2017, and conflicting national standards shall be withdrawn at the latest by August 2017.

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 EN 868-2:2009.

Annex A provides details of significant technical changes between this European Standard and the previous edition.

EN 868 consists of the following parts, under the general title *Packaging for terminally sterilized medical devices*:

— *Part 2: Sterilization wrap — Requirements and test methods;*

— *Part 3: Paper for use in the manufacture of paper bags (specified in* EN 868-4*) and in the manufacture of pouches and reels (specified in* EN 868-5*) — Requirements and test methods;*

— *Part 4: Paper bags — Requirements and test methods;*

— *Part 5: Sealable pouches and reels of porous materials and plastic film construction — Requirements and test methods;*

— *Part 6: Paper for low temperature sterilization processes — Requirements and test methods;*

— *Part 7: Adhesive coated paper for low temperature sterilization processes — Requirements and test methods;*

— *Part 8: Re-usable sterilization containers for steam sterilizers conforming to* EN 285 *— Requirements and test methods;*

— *Part 9: Uncoated nonwoven materials of polyolefines — Requirements and test methods;*

— *Part 10: Adhesive coated nonwoven materials of polyolefines — Requirements and test methods.*

In addition, ISO/TC 198 "Sterilization of health care products" in collaboration with CEN/TC 102 "Sterilizers and associated equipment for processing of medical devices" has prepared the series EN ISO 11607 "Packaging for terminally sterilized medical devices". The EN ISO 11607- series specifies general requirements for materials, sterile barrier systems and packaging systems (Part 1) and validation requirements for forming, sealing and assembly processes (Part 2).

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

Introduction

The EN ISO 11607- series consists of two parts under the general title “Packaging for terminally sterilized medical devices”. Part 1 of this series specifies general 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 to the point of use. Part 2 of this series specifies validation requirements for forming, sealing and assembly processes.

General requirements for all types of sterile barrier systems are provided by EN ISO 11607-1.

The EN 868 series can be used to demonstrate compliance with one or more of the requirements specified in EN ISO 11607-1.

CEN/TC 102/WG 4 also appreciates the initiatives of CEN with regard to the minimization of adverse environmental impacts by standards. It was agreed that this subject should be given priority during the next edition of the EN ISO 11607- series that is the basic reference for all parts of the EN 868 series.

1 Scope

This European Standard specifies test methods and values for materials for sterile barrier systems and/or packaging systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use.

Other than the general requirements as specified in EN ISO 11607-1 and EN ISO 11607-2 this part of EN 868 specifies materials, test methods and values that are specific to the products covered by this European Standard.

While materials specified in 4.2.2.1 to 4.2.2.3 of this part of EN 868 are intended for single use, the materials specified in 4.2.2.4 are intended for reuse.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 20187, *Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples (ISO 187)*

EN 20811, *Textiles — Determination of resistance to water penetration — Hydrostatic pressure test (ISO 811)*

EN 29073-3, *Textiles — Test methods for nonwovens — Part 3: Determination of tensile strength and elongation (ISO 9073-3)*

EN ISO 535, *Paper and board — Determination of water absorptiveness — Cobb method (ISO 535)*

EN ISO 536, *Paper and board — Determination of grammage (ISO 536)*

EN ISO 1924-2, *Paper and board — Determination of tensile properties — Part 2: Constant rate of elongation method (20 mm/min) (ISO 1924-2)*

EN ISO 1974, *Paper — Determination of tearing resistance — Elmendorf method (ISO 1974)*

EN ISO 2758, *Paper — Determination of bursting strength (ISO 2758)*

EN ISO 9237, *Textiles — Determination of permeability of fabrics to air (ISO 9237)*

EN ISO 11607-1:2009+A1:2014, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006+AMD1:2014)*

EN ISO 13937-1, *Textiles — Tear properties of fabrics — Part 1: Determination of tear force using ballistic pendulum method (Elmendorf) (ISO 13937-1)*

EN ISO 13938-1, *Textiles — Bursting properties of fabrics — Part 1: Hydraulic method for determination of bursting strength and bursting distension (ISO 13938-1)*

ISO 2470-2, *Paper, board and pulps — Measurement of diffuse blue reflectance factor — Part 2: Outdoor daylight conditions (D65 brightness)*