EESTI STANDARD EVS-EN 868-1:1999

Pakkematerjalid ja -süsteemid steriliseeritavatele meditsiinivahenditele. Osa 1: Üldnõuded ja katsemeetodid

Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 868-1:1999 sisaldab Euroopa standardi EN 868-1:1997 ingliskeelset teksti. Käesolev dokument on jõustatud 23.11.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 868-1:1999 consists of the English text of the European standard EN 868-1:1997. This document is endorsed on 23.11.1999 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: Käesolev standard esitab nõuded ja testimismeetodid pakkematerjalidele ja -süsteemidele, mida kasutatakse lõplikult steriliseeritud meditsiinivahendite pakkimiseks ning mis on ette nähtud vahendi steriilsuse säilitamiseks.	**Scope:**

ICS 11.080.30

Võtmesõnad: ekspluatatsiooninõuded, ladustus, meditsiiniaparatuur, pakkimine, steriliseerimine, tehnilised andmed, ühtesobivus

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 868-1

February 1997

ICS 11.080; 55.040

Descriptors: Packaging material, medical devices, sterilization, testing, requirements.

English version

Packaging materials and systems for medical devices which are to be sterilized

Part 1: General requirements and test methods

Matériaux et systèmes d'emballages pour les dispositifs médicaux devant être stérilisés – Partie 1: Exigences générales et méthodes d'essai

Verpackungsmaterialien und -systeme für zu sterilisierende Medizinprodukte – Teil 1: Allgemeine Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 1997-01-27.

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.

The European Standards exist 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, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Contents

Foreword

This European Standard has been prepared by 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 August 1997, and conflicting national standards shall be withdrawn at the latest by August 1997.

This European Standard 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 standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

This Standard is the first of a series of Draft European Standards concerned with packaging materials and systems for medical devices which are to be sterilized. These other Draft European Standards currently are:

prEN 868-2	Packaging materials and systems for medical devices which are to be sterilized – Part 2: Sterilization wrap – Requirements and test methods
prEN 868-3	Packaging materials and systems for medical devices which are to be sterilized – Part 3: Paper for use in the manufacture of paper bags (specified in Part 4 of this Standard) and in the manufacture of pouches and reels (specified in Part 5 of this Standard) – Requirements and test methods
prEN 868-4	Packaging materials and systems for medical devices which are to be sterilized – Part 4: Paper bags – Requirements and test methods
prEN 868-5	Packaging materials and systems for medical devices which are to be sterilized – Part 5: Heat sealable pouches and reel material manufactured from paper and plastic – Requirements and test methods
prEN 868-6	Packaging materials and systems for medical devices which are to be sterilized – Part 6: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation – Requirements and test methods
prEN 868-7	Packaging materials and systems for medical devices which are to be sterilized – Part 7: Adhesive coated paper for the manufacture of heat sealable packs for medical use for sterilization by ethylene oxide or irradiation – Requirements and test methods
prEN 868-8	Packaging materials and systems for medical devices which are to be sterilized – Part 8: Re-usable containers for steam sterilizers conforming to prEN 285 – Requirements and test methods

Introduction

This standard specifies general requirements and test methods for all packaging materials and systems intended for use as packaging for medical devices which are to be terminally sterilized in their packaging.

Subsequent standards in this series (prEN 868-2 et sequence) specify particular requirements for a range of commonly used packaging materials and systems. It is intended that compliance with one of the subsequent particular standards can be used to demonstrate conformance with one or more of the requirements of this part (general requirements) as specified in the particular standard.

The adequacy of a packaging system depends additionally on the manner in which each unit is closed or sealed. Attention is drawn to the need to validate and monitor the packaging process (see also European Standards on quality systems and ISO 11607).

1 Scope

1.1 This European Standard specifies the requirements and test methods for packaging materials and systems:

- which are used for packaging of medical devices which are to be terminally sterilized; and
- which are intended to maintain sterility of the device.

NOTE 1: This standard has been developed as a means to show compliance with relevant European Directives. If health care facilities e. g. hospitals do not place medical devices on the market, they are not covered by these Directives. Nevertheless, such health care facilities can fulfil the same requirements as manufacturers but can use alternative means to demonstrate conformity to this standard.

NOTE 2: Compliance with other Parts of prEN 868 series can be used to demonstrate compliance with one or more of the requirements of this standard.

1.2 This standard does not apply to packaging materials and systems used for packaging aseptically manufactured products.

1.3 This European Standard does not describe a quality assurance system for control of all stages of manufacture.

NOTE: Attention is drawn to the standards for quality systems (see e. g. EN ISO 9001, EN ISO 9002, EN 46001 or EN 46002) which control all stages of manufacture including the sterilization process. It is not a requirement of this standard to have a complete quality system during manufacture but certain elements of such a system can be applied.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 550
Sterilization of medical devices – Validation and routine control of ethylene oxide sterilization

EN 552
Sterilization of medical devices – Validation and routine control of sterilization by irradiation

EN 554
Sterilization of medical devices – Validation and routine control of sterilization by moist heat

EN 20187
Paper, board and pulps – Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples (ISO 187 : 1990)