Biological systems for testing sterilizers and sterilization processes - Part 7: Particular requirements for self-contained biological indicator systems for use in moist heat sterilizers

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EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 866-7:2000 sisaldab Euroopa standardi EN 866-7:1999 ingliskeelset teksti. Käesolev dokument on jõustatud 16.06.2000 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 866-7:2000 consists of the English text of the European standard EN 866-7:1999. This document is endorsed on 16.06.2000 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This standard specifies requirements for self-contained biological indicator systems intended for use in monitoring the performance of moist heat sterilizers operating at temperatures in excess of 100 deg.C	**Scope:** This standard specifies requirements for self-contained biological indicator systems intended for use in monitoring the performance of moist heat sterilizers operating at temperatures in excess of 100 deg.C

ICS 11.080

Võtmesõnad:

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 866-7

December 1999

ICS 11.080

English version

Biological systems for testing sterilizers and sterilization processes

Part 7: Particular requirements for self-contained biological indicator systems for use in moist heat sterilizers

Systèmes biologiques pour l'essai des stérilisateurs et les procédés de stérilisation – Partie 7: Exigences particulières pour les systèmes autonomes d'indicateurs biologiques destinés à être utilisés dans des stérilisateurs à la vapeur d'eau

Biologische Systeme für die Prüfung von Sterilisatoren und Sterilisationsverfahren – Teil 7: Spezielle Anforderungen an Bio-Indikator-Einheiten für den Gebrauch in Dampf-Sterilisatoren

This European Standard was approved by CEN on 1999-06-19.

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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the 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

Ref. No. EN 866-7 : 1999 E

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.

EN 866 consists of the following Parts under the general title "Biological systems for testing sterilizers and sterilization processes"

Part 1: General requirements
Part 2: Particular systems for use in ethylene oxide sterilizers
Part 3: Particular systems for use in moist heat sterilizers
Part 4: Particular systems for use in irradiation sterilizers
Part 5: Particular systems for use in low temperature steam and formaldehyde sterilizers
Part 6: Particular systems for use in dry heat sterilizers
Part 7: Particular requirements for self-contained systems for use in moist heat sterilizers
Part 8: Particular requirements for self-contained systems for use in ethylene oxide sterilizers

In addition CEN/TC 102 Working Group 7 has prepared EN 867 consisting of the following parts under the general title "Non-biological systems for use in sterilizers"

Part 1: General requirements
Part 2: Process indicators (Class A)
Part 3: Specification for Class B indicators for use in the Bowie and Dick Test
Part 4: Specification for indicators as an alternative to the Bowie and Dick test for the detection of steam penetration (in preparation)
Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S (in preparation)

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 June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.

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

Introduction

This European standard specifies the performance requirements for self-contained biological indicator systems supplied ready for use. These systems are intended for use primarily as routine monitors. When it is intended to use self-contained biological indicators in routine monitoring, the chosen indicator system should be employed along with any other chosen indicator system during the process development and validation stages. EN 866-3 specifies the performance requirements for biological indicators supplied ready for use and for suspensions of test organisms supplied either for the preparation of biological indicators or for the inoculation of product for use in validation studies on, and routine monitoring of, moist heat sterilization processes.

The use of the indicators specified in this standard are described, inter alia, in EN 285.

The biological indicators specified in this standard are not intended for use in any process other than moist heat sterilization. The use of a biological indicator in a process other than that stated by the manufacturer can give dangerously misleading results.

The use of a biological system for testing a sterilization process does not allow necessarily the same level of sensitivity in response to inadequate levels of all the critical variables of the process.

The performance of a biological indicator can be affected by the conditions of storage prior to use, the methods of use and the techniques employed after exposure to the process. For these reasons, the recommendations of the manufacturer for storage and use should be followed and biological indicators should be transferred to the specific recovery conditions as soon as possible after exposure to the process. Biological indicators should not be used beyond any expiry date stated by the manufacturer.

Biological indicators should always be used in combination with a physical and/or chemical monitoring in demonstrating the efficacy of a sterilizing process. When a physico-chemical variable of a sterilizing process is outside its specified limits, a sterilization cycle should always be regarded as unsatisfactory, (see also EN 554) irrespective of the results obtained from the biological indicator.

1 Scope

This Part of EN 866 specifies the requirements for self-contained biological indicator systems intended for use in monitoring the performance of moist heat sterilizers operating at temperatures in excess of 100 °C.

NOTE 1: EN 285 specifies the performance and test requirements for large steam sterilizers for porous loads and wrapped goods.

NOTE 2: Hermetically sealed ampules containing micro-organisms suspended in a growth medium with colour change indicator are only suitable for use in sterilizers intended to process aqueous liquids in sealed containers and are not included within this standard.

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 285 : 1996
Sterilization – Steam sterilizers – Large sterilizers

EN 866-1 : 1997
Biological systems for testing sterilizers and sterilization processes – Part 1: General requirements