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National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 867-5:2001

ICS 11.080.10

NON-BIOLOGICAL SYSTEMS FOR USE IN STERILISERS - PART 5: SPECIFICATION FOR INDICATOR SYSTEMS AND PROCESS CHALLENGE DEVICES FOR USE IN PERFORMANCE TESTING FOR SMALL STERILISERS TYPE B AND TYPE S

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EUROPEAN STANDARD
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EN 867-5

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English version

Non-biological systems for use in sterilizers - Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S

Systèmes non biologiques destinés à être utilisés dans des stérilisateurs - Partie 5. Spécifications des systèmes indicateurs et dispositifs d'épreuve de procédé destines a être utilisés pour les essais de performances relatifs aux petits stérilisateurs de Type B et de Type S

Nichtbiologische Systeme für den Gebrauch in Sterilisatoren - Teil 5: Festlegungen von Indikatorsystemen und Prufkorpern für die Leistungsprüfung von Klein-Sterilisatoren vom Typ B und vom Typ S

This European Standard was approved by CEN on 25 July 2001.

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 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 Management Centre has the same status as the official versions.

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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of an identical text or by endorsement, at the latest by February 2002, and conflicting national standards shall be withdrawn at the latest by February 2002.

This European Standard has been considered by CEN/TC 102 as one of a series of European Standards concerned with non-biological indicators used in the testing, monitoring and routine operation of sterilizers. These standards are:

EN 867-1	*Non-biological systems for use in sterilizers – Part 1: General requirements*
EN 867-2	*Non-biological systems for use in sterilizers – Part 2: Process indicators (Class A)*
EN 867-3	*Non-biological systems for use in sterilizers – Part 3: Specification for Class B indicators for use in the Bowie and Dick test*
EN 867-4	*Non-biological systems for use in sterilizers – Part 4: Specification for indicators as an alternative to the Bowie and Dick test for the detection of steam penetration*
prEN 867-5	*Non-biological systems for use in sterilizers – Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S*

In addition CEN/TC 102 Working Group 7 has prepared a series of European Standards describing biological indicators for use in sterilizers. These European Standards are:

EN 866-1	*Biological systems for testing sterilizers and sterilization processes – Part 1: General requirements*
EN 866-2	*Biological systems for testing sterilizers and sterilization processes – Part 2: Particular systems for use in ethylene oxide sterilizers*
EN 866-3	*Biological systems for testing sterilizers and sterilization processes – Part 3: Particular systems for use in moist heat sterilizers*
EN 866-4	*Biological systems for testing sterilizers and sterilization processes – Part 4: Particular systems for use in irradiation sterilizers*
EN 866-5	*Biological systems for testing sterilizers and sterilization processes – Part 5: Particular systems for use in low temperature steam and formaldehyde sterilizers*
EN 866-6	*Biological systems for testing sterilizers and sterilization processes – Part 6: Particular systems for use in dry heat sterilizers*
EN 866-7	*Biological systems for testing sterilizers and sterilization processes – Part 7: Particular requirements for self-contained biological indicator systems for use in moist heat sterilizers*
EN 866-8	*Biological systems for testing sterilizers and sterilization processes – Part 8: Particular requirements for self-contained biological indicator systems for use in ethylene oxide sterilizers*

The annexes A, B, C and D are normative.

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.

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Introduction

The indicators and process challenge devices described in this European Standard are intended specifically for use in carrying out tests on small steam sterilizers, Type B or Type S.

prEN 13060 Parts 2 and 4 specify requirements and tests for small steam sterilizers Type B which are intended to process solid products, hollow products, and porous products any of which may be wrapped in one or more layers of sterilization grade packaging materials (see EN 868) and for small steam sterilizers Type S which may also be specified by the manufacturer of the small steam sterilizer as intended to process hollow products and/or porous products.

Small sterilizers unable to accommodate a sterilization module (600 mm x 300 mm x 300 mm) cannot be tested using the tests described in EN 285:1996 for large sterilizers for wrapped goods and porous loads either because the chamber size is unable to accommodate the standard test packs or because the efficacy of the tests is impaired when the test pack occupies a large proportion of the chamber volume.

The indicator systems described in this European Standard are intended to be used, in conjunction with the appropriate process challenge device, to demonstrate the rapid and complete penetration of steam into the process challenge device. The construction of the process challenge device and the performance of the indicator are designed to ensure that penetration of steam in the load within the sterilizer will provide adequate assurance that steam penetration will occur in routine loads.

1 Scope

This European Standard specifies the performance requirements and test methods for non-biological indicator systems, including the process challenge devices within which they are intended to function, to be used for testing the steam penetration performance of small steam sterilizers, Type B or Type S where appropriate. The test systems specified are intended for use only in small steam sterilizers Type B conforming to prEN 13060-2 and having a usable chamber space greater than 10 l and for small steam sterilizers Type S conforming to prEN 13060-4 also having a usable chamber space greater than 5 l.

Non-biological indicator systems and the associate process challenge devices are specified for various types of load. The possible loads are considered in two classes: Porous loads, which can be wrapped or unwrapped, or hollow instrument loads, which also can be wrapped or unwrapped.

The relevant section of this European Standard on porous loads specifies the requirements for:

– a standard process challenge device to be used in the small load test for porous loads in small steam sterilizers;

– an indicator system for use in the porous load process challenge device. An indicator for this purpose is a Class B indicator as described in EN 867-1.

– an indicator employing an alternative process challenge device equivalent to the porous load process challenge device.

The relevant section of this European Standard on hollow instruments specifies the requirements for:

– hollow load process challenge devices to be used to simulate hollow instrument loads as defined in prEN 13060-4;

– an indicator system, for use in one of the hollow load process challenge device, for assessing steam penetration in a wrapped load of hollow instruments. An indicator for this purpose is a Class B indicator as described in EN 867-1.

The process challenge devices described in this standard are intended for use only in sterilizers of sufficient size to accommodate the process challenge device with no part of the process challenge device closer than 20 mm from the vessel wall; in the case of the porous load process challenge device the total internal volume of the vessel is not less than 10 l.

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