

Non-biological systems for use in sterilizers

Part 3. Specification for Class B indicators for use in the Bowie and Dick test

The European Standard EN 867-3 : 1997 has the status of a
British Standard

ICS 11.080

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by Technical Committee LBI/35, Sterilizers, autoclaves and disinfectors, to Subcommittee LBI/35/3, Sterilization indicators, upon which the following bodies were represented:

- ABHI Special Interest Section (Sterilizers and Disinfectors)
- Association of British Healthcare Industries
- BLWA Ltd. (the Association of the Laboratory Supply Industry)
- Department of Health (Medical Devices Agency)
- European Sterilization Packaging Association (UK)
- Medical Sterile Products Association
- Public Health Laboratory Service
- Royal College of Pathologists
- Royal Pharmaceutical Society of Great Britain

This British Standard, having been prepared under the direction of the Sector Board for Materials and Chemicals, was published under the authority of the Standards Board and comes into effect on 15 October 1997

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Amendments issued since publication

Amd. No.	Date	Text affected
10589 corrigendum	January 2000	Correction to subclause 6.1

The following BSI references relate to the work on this standard:
Committee reference LBI/35/3
Draft for comment 92/57873 DC

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National foreword

This Part of BS EN 867 has been prepared by Subcommittee LBI/35/3, and is the English language version of EN 867-3 : 1997 *Non-biological systems for use in sterilizers — Part 3: Specification for Class B indicators for use in the Bowie and Dick test*, including its corrigendum May 1998, published by the European Committee for Standardization (CEN).

Cross-references

Publication referred to	Corresponding British Standard
EN 285 : 1996	BS EN 285 : 1997 <i>Sterilization — Steam sterilizers — Large sterilizers</i>
EN 867-1 : 1997	BS EN 867 <i>Non-biological systems for use in sterilizers</i>
EN 20187 : 1993	BS EN 867-1 : 1997 <i>General requirements</i>
	BS EN 20187 : 1993 <i>Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples</i>
EN ISO 9001 : 1994	BS EN 20187 : 1993 <i>Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples</i>
	BS EN ISO 9001 : 1994 <i>Quality systems — Model for quality assurance in design, development, production, installation and servicing</i>
ISO 5-1	BS 1384 <i>Photographic density measurements</i>
	BS 1384 : Part 1 : 1985 <i>Guide for terms, symbols and notations</i>
ISO 5-3 : 1995	BS ISO 5 <i>Photography — Density measurements</i>
ISO 5-4 : 1995	BS ISO 5-3 : 1995 <i>Spectral conditions</i>
ISO 2248 : 1985	BS ISO 5-4 : 1995 <i>Geometric conditions for reflection density</i>
	BS EN 2248 : 1993 <i>Complete, filled transport packages — Method for determination of resistance to vertical impact by dropping</i>
ISO 5457	BS 3429 : 1984 <i>Specification for sizes of drawing sheets</i>
ISO 5636-3 : 1992	BS 6538 <i>Air permeance of paper and board</i>
	BS 6538 : Part 2 : 1992 <i>Method for determination of air permeance using the Bendtsen apparatus</i>

Attention is also drawn to BS 7720 : 1995 *Specification for non-biological sterilization indicators equivalent to the Bowie and Dick test*.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 12, an inside back cover and a back cover.

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Descriptors: Medical equipment, sterilizers, tests, sterilization, water vapour, specifications, chemical indicators, packing, labelling, quality assurance

English version

Non-biological systems for use in sterilizers — Part 3: Specification for Class B indicators for use in the Bowie and Dick test

Systèmes non-biologiques destinés à être utilisés
dans des stérilisateurs —
Partie 3: Spécification pour les indicateurs de la
Classe B destinés à être utilisés dans l'essai
de Bowie-Dick

Nichtbiologische Systeme für en Gebrauch in
Sterilisatoren —
Teil 3: Festlegungen für Indikatoren der Klasse B für
den Bowie-Dick-Test

This European Standard was approved by CEN on 1997-01-10. 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.

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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 United Kingdom.

CEN

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

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

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 standard is one of a series of European Standards concerned with non-biological systems for testing 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*

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*
- prEN 866-4 *Biological systems for testing sterilizers and sterilization processes — Part 4: Particular systems for use in irradiation sterilizers*
- prEN 866-5 *Biological systems for testing sterilizers and sterilization processes — Part 5: Particular systems for use in low temperature steam and formaldehyde sterilizers*
- prEN 866-6 *Biological systems for testing sterilizers and sterilization processes — Part 6: Particular systems for use in dry heat sterilizers*

- prEN 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*
- prEN 866-8 *Biological systems for testing sterilizers and sterilization processes — Part 8: Particular requirements for self-contained biological systems for use in ethylene oxide sterilizers*

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).

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.