

## **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**

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## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 867-4:2001 sisaldab Euroopa standardi EN 867-4:2000 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 04.04.2001 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 867-4:2001 consists of the English text of the European standard EN 867-4:2000.</p> <p>This document is endorsed on 04.04.2001 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p><b>Käsitlusala:</b> This Standard specifies the performance requirements for a Class B indicator to be used as an alternative to the Bowie and Dick test for steam sterilizers for wrapped goods (instruments etc. and porous loads).</p>	<p><b>Scope:</b> This Standard specifies the performance requirements for a Class B indicator to be used as an alternative to the Bowie and Dick test for steam sterilizers for wrapped goods (instruments etc. and porous loads).</p>
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**Võtmesõnad:** medical, medicine, non-biological, packages, packing, process, sample surveys, specification (approval), specifications, steam sterilization, steam sterilizers, sterilization, sterilization (hygiene), sterilizers, surveillance (approval), testing, tracer methods

**English version**

**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**

Systèmes non-biologiques utilisés dans les stérilisateurs – Partie 4: Spécifications relatives aux indicateurs utilisés en alternative à l'essai de Bowie-Dick pour la détection de la pénétration de vapeur d'eau

Nichtbiologische Systeme für den Gebrauch in Sterilisatoren – Teil 4: Festlegungen für Indikatoren, die alternativ zum Bowie-Dick-Test für den Nachweis der Dampfdurchdringung verwendet werden

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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 document is currently submitted to the Formal Vote.

EN 867 consists 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
- 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 EN 866 consisting 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 biological indicator systems for use in moist heat sterilizers
- Part 8: Particular requirements for self-contained biological systems for use in ethylene oxide sterilizers

## Introduction

The Bowie and Dick test was conceived as a test for successful air removal from high vacuum porous load sterilizers<sup>1)</sup>. A successful Bowie and Dick test indicates rapid and even penetration of steam into the test pack. The presence of air within the pack, due either to an inefficient air removal stage or an air leak during this stage, or non-condensable gases in the steam supply are circumstances which can lead to a failure of the test. The result of the test may also be affected by other factors which inhibit steam penetration. The test does not necessarily demonstrate either achievement of the required temperature or maintenance of that temperature for the required time to achieve sterilization.

A failure of the Bowie and Dick test is not conclusive proof that the fault in the sterilizer is due to air retention, air leakage or non-condensable gases and it can be necessary to investigate other causes of failure.

The Bowie and Dick test is a performance test for steam sterilizers for wrapped goods and porous loads. As such it is performed during the demonstration of conformity of steam sterilizers to EN 285 and as a routine test of performance in EN 554. The method of carrying out the test is described in EN 285.

A test pack for the Bowie and Dick test consists of two components:

- a) a small standardised test load; and
- b) a chemical indicator system to detect the presence of steam (see EN 867-3).

The Bowie and Dick test as originally described<sup>1)</sup> utilized huckaback towels as the material for the test load. The test described in EN 285 uses cotton sheets for this purpose.

Indicators intended as an alternative to the Bowie and Dick Test use different materials for the test load and employ indicator systems specifically formulated for use with the defined test load. This standard specifies the performance of the indicator system in combination with the test load with which it is intended to be used. The test load may be presented with the indicator system already incorporated and intended for single-use or may be intended for multiple use with a new indicator system to be inserted prior to each use.

The indicator for which the performance is specified in this European standard is intended to indicate that steam penetration has been inadequate. The performance of the indicator specified in this European standard should be equivalent, but not necessarily identical, to the performance obtained in a Bowie and Dick test as described in EN 285. Equivalence should be regarded as providing a similar response to steam penetration with any differences being predictable and such that the necessary level of assurance of satisfactory steam penetration is provided. An indicator meeting this specification is not intended to identify which of the potential causes of poor steam penetration was responsible for the failure indicated by the test.

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<sup>1)</sup> Bowie, J.H., Kelsey, J.C., and Thompson, G.R., Lancet, i, p. 586 (1963)

## 1 Scope

This European Standard specifies the performance requirements for a Class B indicator to be used as an alternative to the Bowie and Dick test for steam sterilizers for wrapped goods (instruments, etc. and porous loads).

An indicator complying with this European Standard incorporates a specified material which is used as a test load. This test load may, or may not, be re-usable. This European standard does not specify requirements for the test load but specifies the performance of the indicator system in combination with the test load with which it is intended to be used. The indicator specified in this European standard is intended to identify poor steam penetration but does not indicate necessarily the cause of this poor steam penetration.

The Bowie and Dick test is performed to demonstrate conformity of a steam sterilizer for wrapped goods to EN 285 and may be used as a routine test of performance of such a sterilizer (see EN 554). The method of carrying out the test is described in EN 285.

This European Standard does not include test methods to establish the suitability of these indicators for use in sterilizers in which the air removal stage does not include evacuation below atmospheric pressure.

## 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 (including amendments).

EN 285 : 1996

Sterilization – Steam sterilizers – Large sterilizers

EN 867-1 : 1997

Non-biological systems for use in sterilizers – Part 1: General requirements

EN ISO 9001 : 1994

Quality systems – Model for quality assurance in design/development, production, installation and servicing (ISO 9001 : 1994)

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)

EN 60584-2 : 1993

Thermocouples – Part 2: Tolerances (IEC 60584-2 : 1982 + A1 : 1989)

EN 60751 : 1995

Industrial platinum resistance thermometer sensors (IEC 60751 : 1983 + A1 : 1986)

ISO 5-4 : 1995

Photography – Density measurements – Part 4: Geometric conditions for reflection density

ISO 2248

Packaging – Complete, filled transport packages – Vertical impact test by dropping

ISO 10012-1

Quality assurance requirements for measuring equipment – Part 1: Metrological confirmation system for measuring equipment