

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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National foreword

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This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 8, an inside back cover and a back cover.

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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 stériliseurs et les procédés de stérilisation —
Part 7: Exigences particulières pour les systèmes autonomes d'indicateurs biologiques destinés à être utilisés dans des stériliseurs 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

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Comité Européen de Normalisation
Europäisches Komitee für Normung

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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.

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.

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