



Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 11140-3:2007

Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test

Stérilisation des produits de santé -
Indicateurs chimiques - Partie 3:
Systèmes d'indicateurs de Classe 2 pour
utilisation lors de l'essai de Bowie et Dick

Sterilisation von Produkten für die
Gesundheitsfürsorge - Chemische
Indikatoren - Teil 3: Indikatorsysteme der
Klasse 2 zur Verwendung im Bowie-Dick-

03/2007



National Foreword

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English Version

**Sterilization of health care products - Chemical indicators - Part
3: Class 2 indicator systems for use in the Bowie and Dick-type
steam penetration test (ISO 11140-3:2007)**

Stérilisation des produits de santé - Indicateurs chimiques -
Partie 3: Systèmes d'indicateurs de Classe 2 pour
utilisation lors de l'essai de Bowie et Dick de pénétration de
la vapeur (ISO 11140-3:2007)

Sterilisation von Produkten für die Gesundheitsfürsorge -
Chemische Indikatoren - Teil 3: Indikatorsysteme der
Klasse 2 zur Verwendung im Bowie-Dick-
Dampfdurchdringungstest (ISO 11140-3:2007)

This European Standard was approved by CEN on 14 March 2007.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

This document (EN ISO 11140-3:2007) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with 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of an identical text or by endorsement, at the latest by September 2007, and conflicting national standards shall be withdrawn at the latest by September 2007.

This document supersedes EN 867-3:1997.

This document 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).

The series EN ISO 11140 consists of the following parts under the general title *Sterilization of health care products - Chemical indicators*:

- *Part 1: General requirements*
- *Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test*
- *Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration.*

Attention is drawn to the fact that the series ISO 11140 additionally consists of Part 5: *Class 2 indicators for Bowie and Dick-type air removal tests*. However, this Part of ISO 11140 will not be part of the series EN ISO 11140 because CEN/TC 102 decided not to adopt ISO 11140-5 as a European Standard.

In addition, reference is made to EN 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* and to EN ISO 15882 *Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results*: Both standards are currently being revised under the Vienna Agreement (ISO/TC 198 lead).

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Endorsement notice

The text of ISO 11140-3:2007 has been approved by CEN as EN ISO 11140-3:2007 without any modifications.

**Sterilization of health care products —
Chemical indicators —**

**Part 3:
Class 2 indicator systems for use in the
Bowie and Dick-type steam penetration
test**

Stérilisation des produits de santé — Indicateurs chimiques —

*Partie 3: Systèmes d'indicateurs de Classe 2 pour utilisation lors de
l'essai de Bowie et Dick de pénétration de la vapeur*



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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
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