



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 11140-4:2007

ICS 11.080.01

**STERILIZATION OF HEALTH CARE
PRODUCTS - CHEMICAL INDICATORS - PART
4: CLASS 2 INDICATORS AS AN
ALTERNATIVE TO THE BOWIE AND
DICKTYPE TEST FOR DETECTION OF STEAM
PENETRATION (ISO 11140-4:2007)**

National Standards
Authority of Ireland
Glasnevin, Dublin 9
Ireland

Tel: +353 1 807 3800
Fax: +353 1 807 3838
<http://www.nsai.ie>

Sales
<http://www.standards.ie>

*This Irish Standard was
published under the authority
of the National Standards
Authority of Ireland and
comes into effect on:
18 April 2007*

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11140-4

March 2007

ICS 11.080.01

Supersedes EN 867-4:2000

English Version

**Sterilization of health care products - Chemical indicators - Part
4: Class 2 indicators as an alternative to the Bowie and Dick-
type test for detection of steam penetration (ISO 11140-4:2007)**

Stérilisation des produits de santé - Indicateurs chimiques -
Partie 4: Indicateurs de Classe 2 comme alternative à
l'essai de Bowie et Dick pour la détection de la pénétration
de la vapeur (ISO 11140-4:2007)

Sterilisation von Produkten für die Gesundheitsfürsorge -
Chemische Indikatoren - Teil 4: Indikatoren der Klasse 2,
die alternativ zum Bowie-Dick-Test für den Nachweis der
Dampfdurchdringung verwendet werden (ISO 11140-
4:2007)

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

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 CEN 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 CEN Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

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

EN ISO 11140-4:2007 (E)

Foreword

This document (EN ISO 11140-4:2007) 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 867-4:2000.

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).

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 11140-4:2007 has been approved by CEN as EN ISO 11140-4:2007 without any modifications.

INTERNATIONAL STANDARD

ISO
11140-4

Second edition
2007-03-15

Sterilization of health care products — Chemical indicators —

Part 4:

Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration

Stérilisation des produits de santé — Indicateurs chimiques —

*Partie 4: Indicateurs de Classe 2 comme alternative à l'essai de Bowie
et Dick pour la détection de la pénétration de la vapeur*



Reference number
ISO 11140-4:2007(E)

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