SLOVENSKI STANDARD
SIST EN ISO 11140-3:2007

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Nadomeġļ a:
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Sterilizacija izdelkov za zdravstveno nego – Kemijski indikatorji – 3. del: Sistemi indikatorjev razreda 2 za uporabo pri Bowie-Dickovem preskusu prodiranja pare (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 (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)

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

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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)

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

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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
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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of an identical text or by endorsement, at the latest by September 2007, and conflicting national standards shall be withdrawn at the latest by September 2007.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).

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

INTERNATIONAL STANDARD

ISO 11140-3

Second edition
2007-03-15

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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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11140-3 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11140-3:2000) which has been technically revised.

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*

— *Part 5: Class 2 indicators for Bowie and Dick-type air removal tests*

Introduction

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 conformance of steam sterilizers to EN 285 and as a routine test of performance in ISO 17665-1. The test method is described in EN 285.

A failure of the Bowie and Dick test is symptomatic of a number of potential problems with the sterilizer that could compromise the uniform sterilization of a load to be processed. This failure 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 was conceived as a test for successful air removal from high-vacuum porous-load sterilizers used in the sterilization of health care products [1]. 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 to an inefficient air removal stage, an air leak during this stage or non-condensable gases in the steam supply, is a circumstance which can lead to 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 test pack for the Bowie and Dick test consists of two components:

a) a small standardized test load;

b) a chemical indicator to detect the presence of steam.

The Bowie and Dick test as originally described [1] utilized huckaback towels as the material for the test load. The test as described in EN 285 uses cotton sheets for this purpose.

Because a range of different tests in different countries has historically been termed the Bowie and Dick test, the term “Bowie and Dick-type test” is used in this part of ISO 11140.

Sterilization of health care products — Chemical indicators —

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

1 Scope

This part of ISO 11140 specifies the requirements for chemical indicators to be used in the steam penetration test for steam sterilizers for wrapped goods, e.g. instruments and porous materials. The indicator for this purpose is a Class 2 indicator as described in ISO 11140-1.

Indicators complying with this part of ISO 11140 are intended for use in combination with the standard test pack as described in EN 285. This part of ISO 11140 does not consider the performance of the standard test pack, but does specify the performance of the indicator systems.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5-1, *Photography — Density measurements — Part 1: Terms, symbols and notations*

ISO 5-3, *Photography — Density measurements — Part 3: Spectral conditions*

ISO 5-4:1995, *Photography — Density measurements — Part 4: Geometric conditions for reflection density*

ISO 187:1990, *Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples*

ISO 2248, *Packaging — Complete, filled transport packages — Vertical impact test by dropping*

ISO 5457, *Technical product documentation — Sizes and layout of drawing sheets*

ISO 5636-3, *Paper and board — Determination of air permeance (medium range) — Part 3: Bendtsen method*

ISO 11140-1:2005, *Sterilization of health care products — Chemical indicators — Part 1: General requirements*

ISO/CIE 10526:1999, *CIE standard illuminants for colorimetry*

EN 285:2006, *Sterilization — Steam sterilizers — Large sterilizers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11140-1 apply.

4 General requirements

4.1 The requirements of ISO 11140-1 apply.

4.2 Test samples shall be conditioned in accordance with ISO 187 prior to testing for performance.

5 Indicator system format

The indicator system format shall meet the following requirements.

a) It shall consist of indicator reagent uniformly distributed on a substrate to cover not less than 30 % of the surface area of the substrate. The distance between adjacent areas of indicator reagent shall not exceed 20 mm. The pattern of indicator reagent distribution should permit easy comparison of the colour change at the margin with the colour change in the central region.

b) It shall have an air porosity not less than 1,7 µm/(Pa·s) when tested in accordance with ISO 5636-3 at an air pressure of 1,47 kPa.

c) It shall have sufficient strength to withstand steam sterilization.

Compliance shall be tested in accordance with Annex A.

d) It shall have a substrate of a colour that is uniform to visual observation.

e) It shall have a difference in reflectance density of not less than 0,3 between the substrate and either the changed indicator or the unchanged indicator as specified by the manufacturer.

Compliance shall be tested in accordance with Annex B.

f) It shall permit writing in permanent ink to be made legibly on both processed and unprocessed materials. Markings made before processing shall be legible after processing.

g) It shall be of size A4 in accordance with ISO 5457.

6 Performance requirements

6.1 The indicator shall meet the following requirements.

a) It shall show a uniform colour change complying with 5 e) after exposure to dry saturated steam at 134 ($^{+1,5}_{0}$) °C for 3,5 min ± 5 s or after exposure to dry saturated steam at 121 ($^{+1,5}_{0}$) °C for 15 min ± 5 s or both.

Compliance shall be tested in accordance with Annex C.

b) When placed in the centre of a standard test pack, it shall show a non-uniform colour change when the temperature at the centre of the standard test pack is 2 K lower than the temperature of the chamber drain of the steam exposure apparatus (see Annex H).

Compliance shall be tested in accordance with Annex I.