SLOVENSKI STANDARD
SIST EN ISO 11140-4:2007

01-september-2007

Nadomeġļa:
SIST EN 867-4:2001

Sterilizacija izdelkov za zdravstveno nego – Kemijski indikatorji – 4. del: Indikatorji razreda 2, ki se uporabljajo namesto Bowie-Dickovega preskusa za ugotavljanje prodiranja pare (ISO 11140-4:2007)

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)

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)

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

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11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

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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)

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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 11140-4:2007) 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of an identical text or by endorsement, at the latest by September 2007, and conflicting national standards shall be withdrawn at the latest by September 2007.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

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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 11140-4 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11140-4:2001) 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, are circumstances 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 system 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.

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

This part of ISO 11140 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 it 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 part of ISO 11140 is intended to indicate when steam penetration has been inadequate. The performance of the indicator specified in this part of ISO 11140 should be equivalent, but not necessarily identical, to the performance obtained in the Bowie and Dick-type test as described in ISO 11140-3. 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.

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

1 Scope

This part of ISO 11140 specifies the performance for a Class 2 indicator to be used as an alternative to the Bowie and Dick-type test for steam sterilizers for wrapped health care goods (instruments, etc., and porous loads).

NOTE The Bowie and Dick-type test is used for routine testing of steam sterilizers and validation of steam sterilization processes.

An indicator complying with this part of ISO 11140 incorporates a specified material which is used as a test load. This test load may, or may not, be re-usable. This part of ISO 11140 does not specify requirements for the test load, but specifies the performance of the indicator in combination with the test load with which it is intended to be used. The indicator specified in this part of ISO 11140 is intended to identify poor steam penetration but does not necessarily indicate the cause of this poor steam penetration.

This part of ISO 11140 does not include test methods to establish the suitability of these indicator systems for use in sterilizers in which the air removal stage does not include evacuation below atmospheric pressure.

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 10012-1, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment*

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

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

IEC 60584-2:1982, *Thermocouples. Part 2: Tolerances*

IEC 60584-2/am1:1989, *Amendment 1 — Thermocouples. Part 2: Tolerances*

IEC 60751:1983, *Industrial platinum resistance thermometer sensors*

IEC 60751/am1:1986, *Amendment 1 — Industrial platinum resistance thermometer sensors*

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 and the following apply.

3.1
air pocket
concentration of residual, induced or injected air or non-condensable gases in the standard test pack

3.2
chamber reference temperature
temperature measured at a defined reference point within the steam exposure apparatus

NOTE The defined reference point is usually located in the chamber drain or active chamber discharge.

3.3
exposure time
period for which the chamber reference temperature lies within the sterilization temperature band

3.4
pre-assembled pack
indicator in which the indicator system is incorporated into the test load during the manufacturing process and which is supplied ready for use

3.5
reference fault period
period of 30 s commencing when the chamber reference temperature attains the set operating temperature

3.6
sterilization temperature
minimum temperature of the sterilization temperature band

NOTE The use of the word “sterilization” within this and other definitions is not intended to imply that sterilizing conditions will take place under the test cycle conditions.

3.7
sterilization temperature band
range of temperatures from the sterilization temperature to the maximum allowable temperature which may prevail throughout the load during the holding time

NOTE These temperatures are usually stated in whole degrees centigrade.

3.8
temperature depression
thermodynamic temperature difference in kelvin given by (chamber reference temperature, in degrees centigrade) minus (temperature in the standard test pack, in degrees centigrade)

3.9
test equilibration time
time elapsed after the chamber reference temperature attains the set operating temperature until the temperature within the standard test pack is the same as the chamber reference temperature, within the limits of accuracy of the temperature-measuring equipment

3.10
user-assembled pack
indicator in which the user combines the indicator system with the test load prior to use

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.

4.3 Compliance with the requirements of this part of ISO 11140 shall be determined by establishing conformity with the performance requirements of Clause 6.

4.4 The indicator shall have sufficient strength to withstand steam sterilization and subsequent handling.

Compliance shall be tested in accordance with Annex A.

4.5 Test cycles for demonstrating compliance with the requirements of this part of ISO 11140 shall employ sub-atmospheric, trans-atmospheric and super-atmospheric air removal stages (see Table 1 and B.1, B.2 and B.3) except when the indicator, or indicator system, is intended solely for use with one type of air removal system, in which case only the specified air removal system needs to be used during compliance testing.

4.6 A thermometric recording instrument(s) shall be used in conjunction with temperature sensors to record the temperatures measured in the locations specified in the tests described in this part of ISO 11140. The temperature-measuring equipment used in all test methods for demonstrating compliance with this part of ISO 11140 shall meet the following requirements.

a) Temperature sensors shall be either platinum resistance and comply with Class A of IEC 60751:1983 and IEC 60751 Amendment 1:1986 or a thermocouple and comply with one of the tables of tolerance class 1 of IEC 60584-2:1982 and IEC 60584-2 Amendment 1:1989.

b) The performance characteristic of the temperature sensor shall not be affected by the environment in which it is used, e.g. pressure, steam or vacuum.

c) The temperature sensors shall have a response time in water of $\tau_{90} \leqslant 0{,}5$ s.

d) The temperature measured by all temperature sensors when immersed in a temperature source at a temperature known to within $\pm 0{,}1$ K, and within the sterilization temperature band, shall not differ by more than 0,5 K.

e) The recording instrument shall record the temperature from a minimum of 6 sensors. The sampling interval shall not exceed 2,5 s. All data sampled shall be used for the interpretation of results.

f) The scale range shall include 0 °C to 150 °C. For analogue instruments, the minor mark interval shall not exceed 1 K, the resolution shall be not less than 0,5 K and the chart speed shall be not less than 15 mm/min. Digital instruments shall register and record in increments of not more than 0,1 K.

g) The limit of error of the recording instrument between 0 °C and 150 °C (excluding temperature sensors) shall not exceed 0,25 % when tested in an ambient temperature of (20 ± 3) °C. The additional error due to change in the environmental temperature shall not exceed 0,04 K/K.

h) Calibration shall be carried out using a working or reference standard that is traceable to a national standard or a primary standard. The instrument shall have a valid test certificate.