

# SLOVENSKI STANDARD

## SIST EN ISO 11140-3:2009

01-julij-2009

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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)

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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)

**Ta slovenski standard je istoveten z: EN ISO 11140-3:2009**

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**ICS:**

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general
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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 11140-3**

May 2009

ICS 11.080.01

Supersedes EN ISO 11140-3:2007

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, including Cor  
1:2007)**

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, Cor 1:2007 inclus)

Sterilisation von Produkten für die Gesundheitsfürsorge -  
Chemische Indikatoren - Teil 3: Indikatorsysteme der  
Klasse 2 zur Verwendung im Bowie-Dick-  
Dampfdurchdringungstest (ISO 11140-3:2007,  
einschließlich Cor 1:2007)

This European Standard was approved by CEN on 19 April 2009.

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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## Foreword

The text of ISO 11140-3:2007, including Cor 1:2007 has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11140-3:2009 by 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 November 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document supersedes EN ISO 11140-3:2007.

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 EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

The series EN ISO 11140 consists of the following parts under the general title *Sterilization of health care products - Chemical indicators*: **(standards.iteh.ai)**

- *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 the United Kingdom.

### Endorsement notice

The text of ISO 11140-3:2007, including Cor 1:2007 has been approved by CEN as a EN ISO 11140-3:2009 without any modification.

## Annex ZA (informative)

### Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

**Table ZA – Correspondence between this European Standard and Directive 93/42/EEC on medical devices**

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.1	5, 8, 7, 13	The requirements of ISO 11140-1 apply
6	7.1	
7	13 (except 13.3 a) and 13.6 q))	The relevant Essential Requirement 13.3a) is partly addressed. The relevant Essential Requirement 13.q) is not addressed in this European Standard
7.4	7.1	
8.1	7.1	

**WARNING –** Other requirements and other EU-directives may be applicable to the product(s) falling within the scope of the standard.

INTERNATIONAL  
STANDARD

ISO  
11140-3

Second edition  
2007-03-15

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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**

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*Sterilisation 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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## ISO 11140-3:2007(E)

## 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*:

- SIST EN ISO 11140-3:2009  
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- *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 <sup>[1]</sup>. 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 <sup>[1]</sup> 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.

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