Sterilization of health care products - Chemical indicators - Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers (ISO 11140-6:2022)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11140-6:2022 sisaldab Euroopa standardi EN ISO 11140-6:2022 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11140-6:2022 consists of the English text of the European standard EN ISO 11140-6:2022.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 30.11.2022.	Date of Availability of the European standard is 30.11.2022.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.080.01

EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN ISO 11140-6

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English Version

Sterilization of health care products - Chemical indicators - Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers (ISO 11140-6:2022)

Stérilisation des produits de santé - Indicateurs chimiques - Partie 6: Indicateurs de type 2 et dispositifs d'épreuve de procédé destinés à être utilisés pour les essais de performances relatifs aux petits stérilisateurs à la vapeur d'eau (ISO 11140-6:2022)

Sterilisation von Produkten für die Gesundheitsfürsorge - Chemische Indikatoren - Teil 6: Indikatoren der Klasse 2 und Prüfkörper für die Leistungsprüfung von Dampf-Klein-Sterilisatoren (ISO 11140-6:2022)

This European Standard was approved by CEN on 21 November 2022.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 11140-6:2022 E

European foreword

This document (EN ISO 11140-6:2022) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices” 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 May 2023, and conflicting national standards shall be withdrawn at the latest by May 2023.

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

This document supersedes EN 867-5:2001.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 11140-6:2022 has been approved by CEN as EN ISO 11140-6:2022 without any modification.

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers and associated equipment for processing of medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 11140 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document includes a description of both hollow and porous process challenge devices (PCDs) and their performance requirements, along with methods by which an alternative PCD can be shown to have equivalent performance to that of the reference PCD. Small sterilizers unable to accommodate a sterilization module [rectangular parallelepiped of dimensions 300 mm (height) × 600 mm (length) × 300 mm (width)] cannot be tested using the tests described in EN 285 for large sterilizers for wrapped goods and porous loads because

— the chamber size of a small steam sterilizer according to EN 13060 is unable to accommodate the standard test pack from EN 285, and

— the efficacy of the tests is impaired when the test pack occupies a large proportion of the chamber volume (>20 % chamber volume).

Indicators described in this document are intended to be used in conjunction with appropriate PCDs to show penetration of steam into the PCD. The reference indicator systems and alternative indicator systems pose specified challenges to air removal and steam penetration.

The devices described in this document are intended for use only in small steam sterilizers conforming to EN 13060 to monitor steam penetration in type B cycles and some type S cycles.

NOTE Even though the hollow load was originally designed as a type test in EN 867-5 (withdrawn standard replaced by this document) to test the performance of small steam sterilizers conforming with EN 13060, the same test is also used in other standards, for example, EN 285.

Sterilization of health care products — Chemical indicators —

Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers

WARNING — The use of this document can involve hazardous materials, operations and equipment. It is the responsibility of the user of this document to establish appropriate safety and health practices and determine the applicability of any other restrictions prior to use.

1 Scope

This document specifies the performance requirements and test methods for hollow devices and porous devices as well as the chemical indicators and biological indicators that are utilized within these devices for testing a specific steam penetration performance of type B cycles and some type S cycles of small steam sterilizers according to EN 13060.

NOTE The hollow and porous devices described in this document are not intended for use as surrogate devices for hollow and porous medical devices used in health care facilities.

a) Chemical indicators used with a porous device specified in this document are designed to demonstrate the adequacy of steam penetration into a porous device in small steam sterilizers (see EN 13060).

   This document specifies the requirements for:

   — a reference porous device (RPD) as a reference device by which alternative porous indicator systems (APISs) can be shown to be equivalent in performance according to this document, i.e. a textile test pack in which steam penetration is judged by thermometric means;

   — an alternative porous chemical indicator system equivalent in performance to the RPD, i.e. an APIS, usually commercially manufactured, of any design.

b) Chemical indicators used with a hollow load device specified in this document are designed to demonstrate the adequacy of steam penetration into a narrow lumen (previously known as hollow load A) in small steam sterilizers (see EN 13060).

   This document specifies the requirements for:

   — a reference hollow device (RHD) used as a reference device in this document, i.e. a lumened device with attached capsule in which steam penetration is judged by inactivation or survival of a specified biological indicator;

   — an alternative hollow device:

      — employing the same specific test load as defined for the RHD and a chemical indicator designed specifically for use in the reference hollow test load, i.e. a lumened device with an attached capsule in which steam penetration is judged by visual examination of a chemical indicator;

      — equivalent in performance to the RHD, i.e. an alternative hollow device, usually commercially manufactured, of any design.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

ISO 11138-3, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes*

ISO 11140-1:2014, *Sterilization of health care products — Chemical indicators — Part 1: General requirements*

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 18472, *Sterilization of health care products — Biological and chemical indicators — Test equipment*

EN 285:2015 +A1:2021, *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.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
biological indicator
test system containing viable microorganisms providing a specified resistance to a specified sterilization process

[SOURCE: ISO 11139:2018, 3.29]

3.2
chemical indicator
test system that reveals change in one or more pre-specified process variables based on a chemical or physical change resulting from exposure to a process

Note 1 to entry: See Annex D.

[SOURCE: ISO 11139:2018, 3.43, modified — Note 1 to entry has been added.]

3.3
chemical indicator endpoint
completion of a specified change after a *chemical indicator* (3.2) has been exposed to specified conditions

[SOURCE: ISO 11139:2018, 3.44]

3.4
chemical indicator system
combination of a *chemical indicator* (3.2) and a specific test load

Note 1 to entry: See Annex D.

[SOURCE: ISO 11139:2018, 3.43.1, modified — Note 1 to entry has been added.]