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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

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

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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).

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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).

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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.

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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.

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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.]

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3.5
process challenge device
PCD
item providing a defined resistance to a cleaning, disinfection, or sterilization process and used to assess performance of the process

[SOURCE: ISO 11139:2018, 3.205]

4 Requirements

4.1 General

4.1.1 Unless specified otherwise in this document, the requirements of ISO 11140-1 shall apply.

4.1.2 The chemical indicator, the biological indicator, the hollow device and porous device shall be conditioned in an environment of (50 ± 10) % relative humidity (RH) and (25 ± 5) °C. Means shall be used to ensure the internal volume of the hollow device is conditioned similarly.

4.1.3 Chemical indicators intended for use with reusable, user-assembled hollow devices shall not transfer indicator reagent to the material of the hollow device during processing. Preassembled hollow devices and porous devices, and indicators for single-use or user-assembled devices shall not transfer indicator reagent to the material of the device during processing to an extent which impairs the utility of the device.

4.1.4 A process challenge device (PCD) intended to be reused shall, when used in accordance with the provided instructions for use, meet the relevant requirements of this document, during its specified shelf life.

NOTE 1 Instruction can include restriction on the number of reuses, as well as important information on service, cleaning procedures, the manner of inspection and criteria, maintenance and replacement of components.

To establish conformity to the performance requirements of this document over the shelf life of the PCD, a study shall be conducted by way of a protocol developed before study commencement. This may be either a real-time study, or be accelerated. An example of an accelerated study is given in Annex F.

NOTE 2 Some regulatory authorities will only accept data from real-time studies.

4.1.5 For chemical indicator systems with reusable user-assembled hollow devices, conformance to this document shall be demonstrated for the whole of the usable life of the chemical indicator system as specified by the manufacturer.

4.1.6 Conformance of steam penetration shall be demonstrated by visual examination of the chemical indicator system before and after testing in accordance with the requirements of 4.2.3, 4.4 and 4.5, as appropriate.

4.1.7 The designs of alternative hollow and porous devices are not restricted provided they meet the requirements of 4.2.3, 4.4 and 4.5.

4.2 Porous devices

4.2.1 Reference porous device (RPD)

4.2.1.1 The reference porous device (RPD) shall be a standardised test pack that is used to assess the steam penetration performance of small steam sterilizers.

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