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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

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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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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.