BS EN ISO 11138-3:2017

BSI Standards Publication

Sterilization of health care products — Biological indicators

Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2017)

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National foreword

This British Standard is the UK implementation of EN ISO 11138-3:2017. It supersedes BS EN ISO 11138-3:2009 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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English Version

Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2017)

Stérilisation des produits de santé - Indicateurs biologiques - Partie 3: Indicateurs biologiques pour la stérilisation à la chaleur humide (ISO 11138-3:2017)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische Indikatoren - Teil 3: Biologische Indikatoren für Sterilisationsverfahren mit feuchter Hitze (ISO 11138-3:2017)

This European Standard was approved by CEN on 19 January 2017.

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European foreword

This document (EN ISO 11138-3:2017) 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of an identical text or by endorsement, at the latest by September 2017 and conflicting national standards shall be withdrawn at the latest by September 2017.

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 11138-3:2009.

The standard is a full technical revision of the previous version. The following amendments have been made in comparison with EN ISO 11138-3:2009:

— requirements on population and resistance (clause 9) revised;

— Annex A, in particular A.2.4 step 4 revised;

— informative Annex ZA respective relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered was deleted.

EN ISO 11138 consists of the following parts, under the general title *Sterilization of health care products — Biological indicators*:

— *Part 1: General requirements*

— *Part 2: Biological indicators for ethylene oxide sterilization processes*

— *Part 3: Biological indicators for moist heat sterilization processes*

— *Part 4: Biological indicators for dry heat sterilization processes*

Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes

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Endorsement notice

The text of ISO 11138-3:2017 has been approved by CEN as EN ISO 11138-3:2017 without any modification.

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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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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This third edition cancels and replaces the second edition (ISO 11138-3:2006), which has been technically revised.

A list of all parts of ISO 11138 can be found on the ISO website.

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