BS EN ISO 11138-2:2017

BSI Standards Publication

Sterilization of health care products — Biological indicators

Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)

National foreword

This British Standard is the UK implementation of EN ISO 11138-2:2017. It supersedes BS EN ISO 11138-2:2009 which is withdrawn.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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EUROPEAN STANDARD

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English Version

Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)

Stérilisation des produits de santé - Indicateurs biologiques - Partie 2: Indicateurs biologiques pour la stérilisation à l'oxyde d'éthylène (ISO 11138-2:2017)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische Indikatoren - Teil 2: Biologische Indikatoren für Sterilisationsverfahren mit Ethylenoxid (ISO 11138-2:2017)

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

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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.

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European foreword

This document (EN ISO 11138-2:2017) 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 11138-2:2009.

The standard is a full technical revision of the previous version. The following amendments have been made in comparison with EN ISO 11138-2:2009:

— requirements on population and resistance (clause 9) revised, e.g. information to minimum *D*-value at 30 °C deleted;

— Annex A, in particular A.2.4 step 6 revised;

— informative Annex B on rationale for the inclusion of a second *D*-value and deletion of the requirement for a minimum D-value at 30 °C added;

— 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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