INTERNATIONAL STANDARD

ISO 11135

Second edition
2014-07-15

AMENDMENT 1
2018-10

Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

AMENDMENT 1: Revision of Annex E, Single batch release

Stérilisation des produits de santé — Oxyde d'éthylène — Exigences de développement, de validation et de contrôle de routine d'un processus de stérilisation pour des dispositifs médicaux

AMENDEMENT 1: Révision de l'Annexe E, Libération d'un lot unique

Reference number
ISO 11135:2014/Amd.1:2018(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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*.

As a result of this amendment, the following changes have been made to Annex E:

— clarification on the application of the method i.e. for research and development of new product or for clinical trial product;

— clarification that data resulting from a single batch release study can be used to support a full validation study;

— clarification that temperature and relative humidity sensors should be used to establish conditions in the sterilization load during both the half cycle and the full cycle comprising a single batch release.

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.

Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

AMENDMENT 1: Revision of Annex E, Single batch release

Clause 2

Correct the publication year of ISO 11138-2 from 2009 to 2006.

Add the following and also a footnote “1) Under preparation”.

ISO 11138-7: —[1)] Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results

Annex E

Replace Annex E with the following:

Annex E
(normative)

Single batch release

E.1 General

This annex specifies the requirements for the release of product from a single batch for a sterilization process where there is only sufficient product, at most, for a single sterilization load, for example, during research and development of new product or for clinical trial product. This approach shall only be used to release product to market from multiple batches if it is part of a full validation. Single batch release data can be generated under either a stand-alone protocol for release of that batch, or as one part of a full validation.

NOTE The requirements of ISO 11135 apply for any aspects not specifically addressed in this annex.

E.2 Procedure

E.2.1 Assess the packaged product to determine if it can be assigned to an existing product family for sterilization purposes. This assessment considers product composition, design, packaging, bioburden and load density. The outcome of this assessment, including the rationale for decisions reached, shall be documented.

E.2.2 If the packaged product can be assigned to an existing product family refer to 12.5.2 and D.12.5.11.1.

E.2.3 Where there is no existing product family(ies), or where packaged product cannot be assigned to an existing product family, the rationale for selection and quantity of the samples shall be documented.

E.2.4 A representative number of samples taken from the manufacturing batch shall be selected for bioburden evaluation, internal PCD construction, product test of sterility, EO sterilization residuals, stability tests, functionality tests, packaging tests, biocompatibility tests, and other tests e.g. bacterial endotoxin test, as appropriate.

The number of samples selected for the product test of sterility shall be not less than that used for bioburden determination.

If comparative resistance of the internal PCD versus product bioburden has previously been assessed using a fractional cycle of shorter duration than that of the half cycle in E.2.7, there have been no positive test results from the product test of sterility samples and the bioburden testing demonstrates comparable results (numbers and types), then it is not necessary to perform the product test of sterility for product test samples exposed to the half cycle in E.2.7.

Product samples shall be randomly selected from the manufacturing batch to determine the average bioburden in accordance with ISO 11737-1.

E.2.5 Prepare internal PCDs using BIs that:

— comply with Clause 5 and 9.5 or 9.6 of ISO 11138-2:2006, plus all applicable clauses of ISO 11138-1;

— are shown to be at least as resistant to EO as is the bioburden of product to be sterilized.

If test of sterility samples are not included in the half cycle, the appropriateness of the PCD shall be documented. The PCD shall present a challenge to the sterilization process that is equivalent or greater

