SLOVENSKI STANDARD
SIST EN ISO 11135:2014/oprA1:2017

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Sterilizacija izdelkov za zdravstveno nego - Etilenoksid - Zahteve za razvoj, validacijo in rutinsko kontrolo sterilizacijskih postopkov za medicinske pripomočke - Dopolnilo A1: Revizija Dodatka E (ISO 11135:2014/DAmd 1:2017)

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 (ISO 11135:2014/DAmd 1:2017)

Sterilisation von Produkten für die Gesundheitsfürsorge - Ethylenoxid -Anforderungen an die Entwicklung, Validierung und Lenkung der Anwendung eines Sterilisationsverfahrens für Medizinprodukte (ISO 11135:2014/DAM 1:2017)

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: Titre manque (ISO 11135:2014/DAmd 1:2017)

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DRAFT AMENDMENT
ISO 11135:2014/DAM 1

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

AMENDMENT 1

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

ICS: 11.080.01

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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.

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11135:2014 Amd.1 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This amendment modifies ISO 11135:2014, Annex E.

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

Page 74 and page 75 - Replace Annex E with:

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 to comprise a single sterilization load, for example, during research and development of new product or for clinical trial product. This approach is not intended for routine sterilization. Single batch release data can be used in validation of the sterilization process under an approved protocol.

NOTE Attention is drawn to the possible existence of national or regional regulations for clinical product. Where such regulations are in force, the requirements of these regulations apply.

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, is 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.2.3.1 A representative number of samples taken from the same batch shall be selected for bioburden evaluation, PCD construction, product test of sterility, EO residue tests, 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 should 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.2.3.5, 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.2.3.5.

E.2.3.2 Product Samples shall be randomly selected from the manufacturing batch to determine the average bioburden in accordance with ISO 11737-1.

E.2.3.3 Prepare internal PCDs using BIs that

- comply with ISO 11138-2:2016, Clause 5 and 9.5,
- are shown to be at least as resistant to EO as is the bioburden of product to be sterilized, and
- are placed within an appropriate PCD.

The appropriateness of the PCD shall be documented. The PCD shall present a challenge to the sterilization process that is equivalent or greater than the challenge presented by the natural bioburden at the most difficult to sterilize location within the product. (See D.8.6)

The product test of sterility samples shall be distributed throughout the load.

The number of Internal PCDs should be justified if less than the number specified in Table C.3 for MPQ.

E.2.3.4 Distribute product test of sterility samples (if included), internal PCDs, temperature monitors, humidity monitors and other test samples (e.g. samples for EO residue tests) throughout the sterilization load, including locations where sterilizing conditions are most difficult to achieve.

E.2.3.5 Expose the sterilization load to a half cycle using defined process parameters selected to deliver less lethality than the specified sterilization process.

E.2.3.6 Remove internal PCDs and test biological indicators in accordance with manufacturer's instructions as per ISO 14161.

E.2.3.7 Remove samples for product test of sterility (if included) from the load and subject to tests of sterility in accordance with ISO 11737-2.

E.2.3.8 Aerate and re-equilibrate the load to ambient conditions. The aeration period shall be sufficient to allow EO residues to dissipate to a level that will not adversely affect new PCDs in the full exposure sterilization cycle (see E.2.3.9 and E.2.3.10 below).

The aeration period shall be justified and documented. Data from similar validations can be used for this justification.

E.2.3.9 Distribute new internal PCDs (that are the same type as used in the half cycle), temperature monitors, and humidity monitors throughout the sterilization load, including locations where sterilizing conditions are most difficult to achieve.

E.2.3.10 Process the same load by exposing it to the defined sterilization process where the specified exposure time is at least double that of the half cycle in E.2.3.5 above (i.e. a full sterilization cycle) in the same sterilization chamber.

E.2.3.11 Remove internal PCDs and test biological indicators in accordance with manufacturer's instructions as per ISO 14161.

E.2.3.12 Other test samples should also be removed at an appropriate time after the process (e.g. samples for residue tests, functionality tests, packaging integrity tests, biocompatibility).

E.2.4 The sterilization load can be released from sterilization if the following requirements are met:

a) confirmation that the data recorded during the half cycle meet the half cycle process specification;

b) confirmation that the data recorded during the full cycle meet the full cycle process specification;