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Sterilizacija izdelkov za zdravstveno nego - Etilenoksid - 2. del: Navodilo za uporabo ISO 11135-1 (ISO/TS 11135-2:2008)

Sterilization of health care products - Ethylene oxide - Part 2: Guidance on the application of ISO 11135-1 (ISO/TS 11135-2:2008)

Sterilisation von Produkten für die Gesundheitsfürsorge - Ethylenoxid - Teil 2: Leitfaden zur Anwendung von ISO 11135-1 (ISO/TS 11135-2:2008)

Stérilisation des produits de santé - Oxyde d'éthylène - Partie 2: Directives relatives à l'application de l'ISO 11135-1 (ISO/TS 11135-2:2008)

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Foreword

This document (CEN ISO/TS 11135-2:2008) has been prepared by Technical Committee CEN/TC 204 “Sterilization of medical devices", the secretariat of which is held by BSI, in collaboration with Technical Committee ISO/TC 198 "Sterilization of health care products".

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Endorsement notice

The text of ISO/TS 11135-2:2008 has been approved by CEN as a CEN ISO/TS 11135-2:2008 without any modification.

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ISO/TS 11135-2

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Sterilization of health care products — Ethylene oxide —

Part 2: Guidance on the application of ISO 11135-1

Stérilisation des produits de santé — Oxyde d'éthylène — Partie 2: Directives relatives à l'application de l'ISO 11135-1

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

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ISO/TS 11135-2 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO/TS 11135-2, together with ISO 11135-1, cancels and replaces ISO 11135:1994 and ISO 11135/Cor.1:1994, which have been technically revised.

ISO/TS 11135 consists of the following parts, under the general title *Sterilization of health care products — Ethylene oxide*:

— *Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

— *Part 2: Guidance on the application of ISO 11135-1*

Introduction

This Technical Specification describes some of the methods that may be employed to achieve the requirements contained in ISO 11135-1. This document is not intended as a checklist for assessing compliance with ISO 11135-1, rather it is intended to promote a uniform understanding and implementation of ISO 11135-1 by providing explanations and possible methods for achieving compliance with specified requirements. It highlights important aspects and provides examples.

This Technical Specification addresses ethylene oxide (EO) sterilization in both the industrial and health care facility settings, and it acknowledges the similarities and differences between the two applications.

Among the similarities are the common need for quality systems, staff training, and proper safety measures. The major differences relate to the unique physical and organizational conditions in health care facilities, and to the initial condition of re-usable devices being presented for sterilization.

Health care facilities differ from medical device manufacturers in the physical design of processing areas, in the equipment used, and in the availability of personnel with adequate levels of training and experience. The primary function of the health care facility is to provide patient care; medical device reprocessing is just one of a myriad of activities that are performed to support that function.

In terms of the initial condition of medical devices, medical device manufacturers generally sterilize large numbers of similar devices that have been produced from virgin material. Health care facilities, on the other hand, must handle and process both new medical devices and re-usable medical devices of different descriptions and with varying levels of bioburden. They are therefore faced with the additional challenges of cleaning, evaluating, preparing and packaging a medical device prior to sterilization. In this document, alternative approaches and guidance specific to health care facilities are identified as such.

In general, moist heat sterilization (also known as steam sterilization) is the method of choice for medical devices and supplies that are sterilized in health care facilities. However, EO gas and its mixtures are effective sterilants that are primarily used for heat- and moisture-sensitive medical devices that cannot be steam sterilized.

For ease of reference, the numbering in this technical specification corresponds to that in ISO 11135-1.

Sterilization of health care products — Ethylene oxide —

Part 2:
Guidance on the application of ISO 11135-1

1 Scope

This Technical Specification provides guidance for the requirements in ISO 11135-1:2007. It does not repeat the requirements and is not intended to be used in isolation.

The exclusions in ISO 11135-1 apply also to this Technical Specification.

For ease of reference, the clause numbering in this Technical Specification corresponds to that in ISO 11135-1:2007. Further guidance for the requirements given in ISO 11135-1 is also included in Annex C of ISO 11135-1:2007 and should be used in conjunction with this Technical Specification.

This guidance document is intended for people who have a basic knowledge of the principles of EO sterilization but may need help in determining how to best meet the requirements contained in ISO 11135-1. This document is not intended for people lacking a basic knowledge of the principles of EO sterilization.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11135-1:2007, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11138-2:2006, *Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes*

ISO 11140-1:2005, *Sterilization of health care products — Chemical indicators — Part 1: General requirements*

ISO 11737-1, *Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products*

ISO 13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions in ISO 11135-1 and the following apply.

3.1
dunnage
material used to mimic all or part of a sterilization load

3.2
health care facility
set of physical infrastructure elements intended to support the delivery of specific health-related services

3.3
processing group
collection of products or product families that can be sterilized in the same EO sterilization process

NOTE All products within the group have been determined to present an equal or lesser challenge to the sterilization process than the challenge device for that group.

3.4
EO product family
collection of products that are determined to be similar or equivalent for validation purposes

3.5
re-usable medical device
medical device designated or intended by the manufacturer as suitable for reprocessing and re-use

NOTE This is not a medical device that is designated or intended by the manufacturer for single use only.

3.6
single use medical device
medical device that is designated or intended by the manufacturer for one-time use only

3.7
sterilization specialist
person with knowledge of the sterilization technology being utilized and its effects upon materials and microorganisms

NOTE This level of knowledge has been obtained by both practical and theoretical means and the person does not require guidance on the basic principles of the technology involved.

4 Quality management systems

4.1 Documentation

4.1.1 No guidance offered.

4.1.2 No guidance offered.

4.2 Management responsibility

4.2.1 Each organization should establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities.

4.2.2 No guidance offered.

4.3 Product realization

4.3.1 Purchasing procedures in a health care facility should ensure that re-usable medical devices are supplied with validated instructions for cleaning, disinfection, sterilization and aeration as specified in ISO 17664.

4.3.2 For those facilities that do not fully comply with ISO 13485, such as health care facilities, procedures for identification of product and maintenance of traceability, should include the labelling of each item or package prior to sterilization with a lot control identifier that includes the following information:

a) the sterilizer ID or code;

b) the date of sterilization;

c) the cycle number (i.e. the cycle run of the day or sterilizer).

It is recommended that the identity of the person who assembled the pack also be included on the identifier, to allow for further investigation if a problem should arise.

Lot identification information enables personnel to retrieve items in the event of a recall and to trace problems to their source.

4.3.3 No guidance offered.

4.4 Measurement, analysis and improvement — Control of non-conforming product

No guidance offered.

5 Sterilizing agent characterization

5.1 Sterilizing agent

EO is a highly penetrative gas that will permeate most packaging materials and polymeric materials. Widely recognized compositions include 100 % EO and blends with carbon dioxide or nitrogen. The storage conditions for EO should be in accordance with the EO manufacturer's recommendations and all applicable regulations.

5.2 Microbicidal effectiveness

No guidance offered.

5.3 Materials effects

No guidance offered.

5.4 Environmental considerations

5.4.1 EO is toxic, flammable and explosive; therefore, extreme caution should be used during its storage, handling and use.

5.4.2 Effluent gas should be discharged through an EO-gas treatment system, such as a catalytic oxidiser, wet acid scrubber or thermal oxidiser.

When choosing a diluent, its ozone depleting potential should be taken into consideration.