Irish Standard Recommendation
S.R. CEN ISO/TS 16775:2014

Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2 (ISO 16775:2014)

S.R. CEN ISO/TS 16775:2014

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Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2 (ISO 16775:2014)

Emballages des dispositifs médicaux stérilisés au stade terminal - Lignes directrices relatives à l'application de l'ISO 11607-1 et l'ISO 11607-2 (ISO 16775:2014)

Verpackungen für in der Endanwendung sterilisierte Medizinprodukte - Leitfaden für die Anwendung von ISO 11607-1 und ISO 11607-2 (ISO 16775:2014)

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Contents

Page

Foreword **3**

Foreword

This document (CEN ISO/TS 16775:2014) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 “Sterilizers for medical purposes” the secretariat of which is held by DIN.

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The text of ISO/TS 16775:2014 has been approved by CEN as CEN ISO/TS 16775:2014 without any modification.

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ISO/TS 16775

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Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2

Emballages des dispositifs médicaux stérilisés au stade terminal — Lignes directrices relatives à l'application de l'ISO 11607-1 et l'ISO 11607-2

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Contents

Page

Foreword ... **v**

Introduction ... **vi**

1 Scope ... **1**

2 Terms and definitions ... **1**

3 Guidance for health care facilities ... **2**
3.1 Test methods ... 2
3.2 Guidance for conformance to ISO 11607-1 ... 2
3.3 Guidance on conformance to ISO 11607-2, ***Validation requirements for forming, sealing and assembly processes*** ... 10
3.4 Quality system ... 19

4 Guidance for industry ... **20**
4.1 General guidance ... 20
4.2 Design inputs ... 20
4.3 Selection and evaluation of materials ... 21
4.4 Sterile barrier system and protective packaging design (packaging system development) ... 22
4.5 Packaging process feasibility evaluation ... 24
4.6 Sterile barrier system design feasibility evaluation ... 25
4.7 Validation of sterile barrier system manufacturing process ... 26
4.8 Packaging system design validation ... 28
4.9 Revalidation ... 29

Annex A (informative) **Selection, evaluation and testing of packaging materials and sterile barrier systems — Guidance for industry and health care facilities** ... **31**

Annex B (informative) **Sterilization considerations — Guidance for industry and health care facilities** ... **39**

Annex C (informative) **Examples of wrapping methods — Guidance for health care facilities** ... **47**

Annex D (informative) **Validation plan documents — Guidance for health care facilities** ... **54**

Annex E (informative) **Installation qualification documentation — Guidance for health care facilities** ... **68**

Annex F (informative) **Operational qualification documentation — Guidance for health care facilities** ... **73**

Annex G (informative) **Performance qualification documentation — Guidance for health care facilities** ... **77**

Annex H (informative) **Addressing worst-case requirements — Guidance for industry and health care facilities** ... **81**

Annex I (informative) **Generating a final packaging system validation protocol — Guidance for industry** ... **83**

Annex J (informative) **Design inputs — Medical device attributes — Guidance for industry** ... **86**

Annex K (informative) **Risk analysis tools — Guidance for industry and health care facilities** ... **91**

Annex L (informative) **Considerations for sampling plans — Guidance for health care facilities** ... **93**

Annex M (informative) **Stability testing (ISO 11607-1:2006, 6.4) — Guidance for industry** ... **95**

Annex N (informative) **Use of the Internet — Guidance for industry and health care facilities** ... **96**

Annex O (informative) **Test method validation — Guidance for industry** ... **97**

Annex P (informative) **Use of contract packagers — Guidance for industry and health care facilities** ... **98**

Annex Q (informative) **Guidance on establishing process parameters — Guidance for industry** **99**

Annex R (informative) **Investigation failure — Guidance for industry and health care facilities** . **105**

Annex S (informative) **Packaging manufacturing process and packaging system design feasibility evaluation — Guidance for industry** **108**

Bibliography **111**

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. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 198, *Sterilization of health care products*.

Introduction

Sterile barrier systems need to ensure the sterility of their contents until opened for use and ensure aseptic presentation.

The sterile barrier system, depending on conditions of handling, distribution or storage, may provide adequate protection for the sterile medical device. In circumstances where the packaged and sterilized device undergoes repeated handling, additional protective packaging may need to be combined with the sterile barrier system to create a packaging system.

Each establishment should evaluate the performance of each sterile barrier system or packaging system before selection and implementation to ensure conditions for sterilization, storage, and handling can be met. Each establishment that manages sterile items should have a documented plan of education on how to store, handle and transport sterile items.

Regional differences in quality management systems and other requirements exist and these might involve different approaches to human resource management. In any case however a sound education process is a key element and facilities should ensure that its personnel are aware of the relevance and importance of their packaging and sterilization activities for the safety of the patient.

ISO 11607-1 specifies the requirements for materials, sterile barrier systems, and packaging systems, including the qualification of the packaging system design and evaluation of that design, ISO 11607-2 specifies the requirements for packaging process validation. Both of these documents provide standards to ensure medical device protection, the ability to sterilize, maintenance of sterile package integrity and aseptic presentation. The scope of each of these standards applies to health care facilities and wherever medical devices are packaged and sterilized. It is recognized that the circumstances of the application of these standards will be different when they are used in a health care facility from when they are used by a medical device manufacturer or reprocessor.

The conditions of use of this guidance may vary widely around the world. ISO 11607-1 and ISO 11607-2 and this guidance document provide a guideline for use, subject to interpretation by circumstance and regulatory environments. In some regions of the world health care facility compliance to the series ISO 11607 is a national or regional regulatory requirement, in some regions the series ISO 11607 is considered guidance for health care facilities. For instance, it is recognized that in certain regions or regulatory applications conformance to ISO 11607-1 may be demonstrated but not conformance to ISO 11607-2, which requires process validation by the user. In other regions, where compliance to both ISO 11607-1 and ISO 11607-2 is a national regulatory requirement, this document will also provide guidance on performing validation. Clause 3 of this guidance document is applicable to health care facilities and Clause 4 is applicable to industry. Further guidance is given in Annexes A to S that may be applicable to health care facilities and/or industry, as indicated.

In Europe ISO 11607-1 assists the conformity assessment procedure for manufacturers and is designed and used as a tool for demonstrating compliance with the relevant essential requirements of the Medical Device Directive. Compliance with the standard is always voluntary.

At the time of publication of this document, Amendments to ISO 11607-1 and ISO 11607-2 are in the ballot process. This guidance document already considers the revised versions with the understanding that specific references to numbering may have changed. Annex B of ISO 11607-1 on test methods has been extensively revised and should be considered when available.

Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2

1 Scope

This Technical Specification provides guidance for the application of the requirements contained in ISO 11607-1 and ISO 11607-2. It does not add to, or otherwise change, the requirements of ISO 11607-1 and/or ISO 11607-2. This is an informative document, not normative. It does not include requirements to be used as basis of regulatory inspection or certification assessment activities.

The guidance can be used to better understand the requirements of ISO 11607-1 and/or ISO 11607-2 and illustrates some of the variety of methods and approaches available for meeting the requirements of those International Standards. It is not required that this document be used to demonstrate compliance with them.

Guidelines are given for evaluation, selection and use of packaging materials, preformed sterile barrier systems, sterile barrier systems and packaging systems. Guidance on validation requirements for forming, sealing and assembly processes is also given.

This Technical Specification provides information for health care facilities (see Clause 3) and for the medical devices industry (see Clause 4).

It does not provide guidance for applications of packaging materials and systems after their opening. In the use of packaging for other purposes such as a “sterile field” or transport of contaminated items, other regulatory standards will apply.

2 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11607-1 and ISO 11607-2 and the following apply.

2.1
packaging system
combination of the sterile barrier system and protective packaging

[SOURCE: ISO/TS 11139:2006, 2.28]

Note 1 to entry: The packaging system includes the sterile barrier system and the protective packaging. However, if the sterile barrier system protects the medical device, facilitates aseptic presentation, and is resilient enough not to require additional protective packaging, the sterile barrier system would also fulfil the requirements of a packaging system. Protective packaging is not always necessary however aseptic opening/presentation has to be ensured in all cases.

2.2
protective packaging
configuration of materials designed to prevent damage to the sterile barrier system and its contents assembly until the point of use

[SOURCE: ISO/TS 11139:2006, 2.37]

Note 1 to entry: National or regional regulations may require that protective packaging is used to avoid the potential contamination of the surgical environment. These regulations may also require that the protective packaging is removed prior to introduction of the sterile barrier system into the surgical environment.