INTERNATIONAL STANDARD

ISO 11607

Second edition
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Packaging for terminally sterilized medical devices

Emballages des dispositifs médicaux stérilisés au stade terminal

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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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11607 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11607:1997), which has been extensively revised.

Annex A forms a normative part of this International Standard. Annexes B and C are for information only.

Introduction

Many global medical device manufacturers and sterile packaging producers seek the ability to comply with both ISO 11607 and EN 868-1, *Packaging materials and systems for medical devices which are to be sterilized — Part 1: General requirements and test method.* However, differences remain where unharmonized ISO and EN standards exist and are referenced in one of the documents.

The goal of this revision is to enable the user to identify the differences that exist between ISO 11607 and EN 868-1. The specific differences are indicated in notes which describe the differences in general terms and provide a reference to specific clauses of EN 868-1:1997. It is necessary that those wishing to demonstrate compliance with EN 868-1 obtain a copy of that standard and not depend on the information on EN 868-1 contained in this International Standard.

The process of designing and developing a package for a terminally sterilized medical device is a complicated and critical endeavor. The device components and the package system should combine to create a total product that performs efficiently, safely, and effectively in the hands of the user.

The specific nature of the medical device; the intended sterilization method(s); and the intended use, shelf life, transport and storage all influence the package design and choice of packaging materials.

Clause 5 of this International Standard specifies the basic attributes required of materials intended for use in packaging for terminally sterilized medical devices while considering the wide range of potential materials, medical devices, packaging designs, and sterilization methods that are available.

Based upon the complexities outlined above, determination that a material is appropriate for packaging of terminally sterilized medical devices should not be made without reference to this International Standard. European standards providing specifications for particular materials are published as the EN 868 series (see Bibliography).

The basic requirements described in this International Standard allow either the producer or the manufacturer to conduct a formal qualification to determine if a potential packaging material meets the performance requirements. Once it has been determined that a material adequately meets the performance requirements, product specifications may be established by the producer, manufacturer or a regulatory body. From that point in time, compliance qualification of the material can be conducted to demonstrate that the material meets these stated specifications.

The development and validation of packaging operations are crucial to ensure package integrity to the users of sterile medical devices. There should be a documented process validation programme demonstrating the efficacy and reproducibility of all sterilization and packaging processes. Along with the sterilization process, some of the packaging operations that can affect package integrity are forming, sealing, capping, or other closure systems, cutting and process handling. Clause 6 provides manufacturers with a framework of activities to validate the process used to make and assemble the package.

The microbial barrier properties of packaging materials, together with suitable forming and sealing, are critical for ensuring package integrity and product safety. If no validated final package challenge method is available or applicable, the barrier properties of materials should be evaluated separately from the effectiveness of forming and sealing.

Clause 7 is intended to assist in the selection of tests and to provide criteria that can be used to evaluate the performance of packages for terminally sterilized medical devices.

It is intended that historical data and supporting rationale be acceptable for use in the verification of requirements of this International Standard.

NOTE EN 868-1 was developed as a means to show compliance with relevant European Directives. If European health care facilities, e.g. hospitals, do not place medical devices on the market, they are not covered by the European Directives.

Nevertheless, such health care facilities can fulfil the same requirements as manufacturers but can use alternative means to demonstrate conformity to EN 868-1.

Packaging for terminally sterilized medical devices

1 Scope

1.1 This International Standard specifies the requirements for single-use materials and reusable containers used for packaging of terminally sterilized medical devices, whether produced industrially or in health care facilities (see clause 6).

1.2 This International Standard outlines principal requirements for packaging process development and validation for the manufacturer of terminally sterilized medical devices (see clause 7). Forming and sealing are considered to be the most critical processes. Other process operations that can affect the final package are addressed also. Guidelines are provided for the most common practices and techniques.

1.3 This International Standard specifies requirements for essential criteria used to evaluate the performance of packages for sterile medical devices (see clause 7). The intent is to provide designers and manufacturers of medical devices with a framework of laboratory tests and evaluations that can be used to qualify the overall performance of the package used to protect device components during handling, distribution and storage.

1.4 This International Standard does not cover all requirements for packaging for products manufactured aseptically; in such cases, additional requirements are necessary to ensure that the packaging and packaging process do not present a source of contamination of the product.

1.5 This International Standard is not applicable to protocols for sampling plans or the number and duration of replicate runs.

NOTE For the purposes of this International Standard, hospitals or other organizations that package medical devices are considered to be manufacturers.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 5636-5:1986, *Paper and board — Determination of air permeance (medium range) — Part 5: Gurley method*

ISO 11140-1:1995, *Sterilization of health care products — Chemical indicators — Part 1: General requirements*

3 Terms and definitions

For the purposes of this International Standard, the following terms and definitions apply.

3.1
bioburden
population of viable microorganisms on an item

3.2
closure
means used to close a package where no seal is formed

EXAMPLE Repeated folding to construct a tortuous path.

3.3
closure integrity
condition of the closure that ensures that the closure presents a microbial barrier to at least the same extent as the rest of the packaging

NOTE In EN 868-1 the definition of this term differs slightly.

3.4
compliance qualification
documented evidence that packaging meets the requirements for packaging for terminally sterilized medical devices based on testing for conformity to an agreed material specification

3.5
development
process of refining a prototype design or process to meet established product criteria

3.6
failure
event in which a component of the package does not perform one or more of its required functions within the specified limits under specified conditions

3.7
failure analysis
logical, systematic examination of an item to identify and analyse the probability, causes and consequences of potential and real failures

3.8
final package
primary containment system in which the product is sterilized (excluding shelf cartons and shipping containers) that protects contents to the intended level over a specific period of time

c.f. **primary package** 3.18

NOTE 1 The intended level may be e.g. a barrier to physical, microbial or chemical challenges.

NOTE 2 In EN 868-1 the term “primary pack” is synonymous with the above definition. In EN 868-1 the term “pack” is synonymous with the term “package” used in this International Standard.

3.9
labelling system
assembly of the package label and any supplied information on usage that is included within or in contact with the final package

3.10
manufacturer
natural or legal person, individual or organization with the responsibility for packaging and/or sterilizing the medical device

3.11
medical device
any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purposes of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

3.12
microbial barrier
attribute of the packaging system that prevents the ingress of microorganisms under specified conditions

NOTE In EN 868-1 the definition of this term differs slightly.

3.13
package integrity
unimpaired physical condition of a final package

3.14
packaging compatibility
attribute of the packaging material and/or system to allow it to achieve the required performance without detrimental effect on the medical device during transport, storage or use

3.15
packaging material
any material used in the fabrication or sealing of a packaging system or primary package

3.16
packaging system
one or more packaging materials assembled into a single unit intended as part or all of a primary package

3.17
performance qualification
documented evidence that packaging meets the appropriate requirements for sterile packaging based on testing of the particular packaging material for compliance with the applicable requirements of this International Standard

3.18
primary package
sealed or closed packaging system that forms a microbial barrier, enclosing a medical device

3.19
producer
natural or legal person, individual or organization with the responsibility for manufacturing the packaging material and/or system

3.20
product
combination of both the medical device and/or additional components with the final package

3.21
qualification
documented evidence that all specified design and performance requirements are met

3.22
revalidation
documented procedure to reconfirm an established validation

3.23
seal
result of joining of packaging layers

NOTE A seal may be created, e.g., by use of adhesives or thermal fusion.

3.24
seal integrity
condition of the seal that ensures that it presents a microbial barrier to at least the same extent as the rest of the packaging

NOTE In EN 868-1 the definition of this term differs slightly.

3.25
seal strength
mechanical strength of the seal

3.26
sterile
free from viable microorganisms

NOTE For the purposes of EN 868-1, the term "sterile" is defined in EN 556.

3.27
sterile fluid-path packaging
system of protective port covers and/or packaging designed to ensure sterility of the portion of the medical device intended for contact with fluids

3.28
sterilization compatibility
attributes of the packaging material and/or system that allow it to both withstand the sterilization process and attain the required conditions for sterilization within the final package

3.29
terminally sterilized
term for medical devices that are sterilized after being completely sealed or enclosed in at least the primary package

3.30
user
natural or legal person, individual or organization having the responsibility for making use of the product

3.31
validation
documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

NOTE Validation is considered to be a total process that includes written protocol, evidence that the equipment as installed meets design criteria and specifications (equipment qualification), use of calibrated instruments to collect data, and evidence that the equipment can deliver the process within specified tolerances under established operating conditions and is reproducible as demonstrated by replicate runs and process challenges (process performance qualification).

4 General requirements

4.1 Quality systems

The activities described within this International Standard shall be carried out within a formal quality system.

NOTE 1 ISO 9001 gives requirements for suitable quality systems. It is not necessary to obtain third party certification of the quality system to fulfil the requirements of this International Standard.

NOTE 2 Health care facilities may use the quality system appropriate for their country or region.

4.2 Sampling

The sampling plans used for selection and testing of packaging materials and/or system shall be chosen by agreement between the producer and manufacturer, e.g. acceptance quality limit (AQL) in accordance with ISO 2859-1 or ISO 186:2002, or statistical process control (SPC). For each plan chosen, a rationale shall be documented.

4.3 Test methods

4.3.1 All test methods used to show compliance with this International Standard shall be validated. The rationale for the selection of test methods, the variables to be determined and the acceptance criteria shall be documented.

4.3.2 For some of the requirements, internationally accepted standardized test methods may be available. The use of these test methods is recommended, but these methods, as well as any other applied methods, shall be validated and documented.

Unless otherwise specified in the test methods for materials, test samples should be conditioned in accordance with ISO 187 at (23 ± 1) °C and (50 ± 2) % relative humidity.

NOTE 1 For compliance with EN 868-1, the above becomes a requirement (EN 868-1:1997, 5.2).

NOTE 2 The test methods listed in annexes B and C of this International Standard do not eliminate the need for validation nor do they exclude other validated test methods.

4.4 Responsibilities for package validation and for compliance and performance qualification

4.4.1 It shall be the responsibility of the manufacturer to ensure that the final package is validated in accordance with this International Standard.

4.4.2 The responsibility for conducting compliance qualification tests on materials shall rest with the producer.

NOTE This does not preclude voluntary assumption of this responsibility by the manufacturer.

4.4.3 The responsibility for conducting performance qualification tests shall rest with the manufacturer.

4.5 Documentation

All procedures, and the results obtained used to demonstrate compliance with the requirements of this International Standard, shall be fully documented and retained securely in accordance with a formal quality system or for a specified period of time, considering factors such as expiry date of the packaging material and/or system, and traceability.

NOTE When compliance with EN 868-1 also is desired, additional documentation is required. (EN 868-1:1997, clause 6).

5 Packaging materials

5.1 General requirements

5.1.1 The intention of packaging for terminally sterilized medical devices is to maintain the sterility of the product with respect to its intended use, shelf life, transport and storage conditions. The conditions under which the packaging material and/or system is produced, stored, transported and handled shall be established, controlled and documented, if applicable, in order to ensure that

— the conditions are compatible with the use for which the packaging material and/or system is designed,

— the performance characteristics of the packaging material and/or system are maintained.

As a minimum, the following shall be considered for all packaging materials and/or systems:

— temperature range;

— pressure range;

— humidity range;

— maximum rate of change of the above, where necessary;

— exposure to sunlight or UV light;

— cleanliness;

— bioburden.

NOTE The bioburden of the packaging material and/or system should be considered when determining the sterilization process parameters.

5.1.2 Raw materials used for the manufacture of packaging materials may be virgin or reclaimed materials, provided that the source, history and traceability of all raw materials, especially recycled materials, is known and controlled to ensure that the finished product will consistently meet the requirements of this International Standard.

NOTE With current commercial technologies, it is unlikely that reclaimed material other than manufacturing waste will be sufficiently controlled to allow its safe use for medical device packaging.

5.1.3 The packaging design and processing requirements shall be reviewed and applied against the material chosen. This should include effects of the sterilization process. Clauses 6 and 7 provide relevant performance criteria.

5.1.4 The following material properties shall be evaluated with appropriate test methods agreed upon by the producer and manufacturer:

a) microbial barrier;

b) toxicological attributes;

c) physical and chemical properties;

d) compatibility with respect to sterilization processes with which the material is intended to be used;

e) compatibility with respect to forming and sealing processes (see clause 6);

f) any shelf-life limitations for pre-sterilization and post-sterilization storage of the packaging material.

5.1.5 Listed in 5.1.6 through 5.1.9 are some essential performance requirements that shall be considered for packaging for terminally sterilized medical devices. This list is not intended to be all-inclusive. The manufacturer shall decide the material characteristics that are necessary for each particular application. Materials which have characteristics not listed in clause 5 can be evaluated using the performance criteria given in clauses 6 and 7.