INTERNATIONAL STANDARD

ISO 14937

First edition
2000-12-15

Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

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Stérilisation des produits de santé — Exigences générales pour la caractérisation d'un agent stérilisant et pour le développement, la validation et la vérification de routine d'un processus de stérilisation pour dispositifs médicaux

ISO 14937:2000
https://standards.iteh.ai/catalog/standards/sist/53c31d27-e13c-4815-b66b-1569d0bc109f/iso-14937-2000

Reference number
ISO 14937:2000(E)

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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 14937 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products.*

Annexes A, B, C and D form a normative part of this International Standard. Annexes E and ZA are for information only.

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Introduction

A sterile medical device is one which is free of viable microorganisms. When it is necessary to supply a sterile medical device, International Standards specifying requirements for validation and routine control of sterilization processes require that adventitious microbiological contamination of a medical device prior to sterilization be minimized. Even so, medical devices produced under standard manufacturing conditions in accordance with the requirements for quality systems (see, for example, ISO 13485 and ISO 13488) or which have been subjected to a cleaning process as part of their reprocessing in a health care establishment may, prior to sterilization, have microorganisms on them, albeit in low numbers. Such products are non-sterile. The purpose of sterilization is to inactivate the microbiological contaminants and thereby transform the non-sterile products into sterile ones.

The kinetics of inactivation of a pure culture of microorganisms by physical and/or chemical agents used to sterilize medical devices can generally best be described by an exponential relationship between the numbers of microorganisms surviving and the extent of treatment with the sterilizing agent. Inevitably this means that there is always a finite probability that a microorganism may survive regardless of the extent of treatment applied. For a given treatment, the probability of survival is determined by the number and resistance of microorganisms and by the environment in which the organisms exist during treatment. It follows that the sterility of any one product in a population subjected to sterilization processing cannot be guaranteed, and the sterility of a processed population has to be defined in terms of the probability of there being a viable microorganism present on a product.

This International Standard describes requirements which will enable sterilizer manufacturers, medical device manufacturers and health care facilities to demonstrate that a process intended to sterilize medical devices has appropriate microbicidal activity, and that this activity is both reliable and reproducible, such that the relationship for the inactivation of microorganisms can be extrapolated with reasonable confidence to low levels of probability of there being a viable microorganism present on a product after sterilization processing. This International Standard does not specify the maximal value to be taken by this probability; specification of this probability is a matter for regulatory authorities and may vary from country to country (see, for example, EN 556 and AAMI ST67).

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Generic requirements of the quality system for design/development, production, installation and servicing are given in the ISO 9000 series and particular requirements for quality systems for medical device production in ISO 13485 and ISO 13488. The standards for quality systems recognize that, for certain processes used in manufacturing or reprocessing, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process monitored routinely and the equipment maintained.

Exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that the product is sterile and, in this respect, suitable for its intended use. Attention is given to a number of factors, including:

a) for a manufacturing process, the microbiological status of incoming raw materials and/or components;

b) the validation and routine control of the cleaning and disinfection procedures used during reprocessing;

c) the control of the environment in which the product is manufactured, assembled and packaged, together with control of personnel and their hygiene; and,

d) the manner in which the items are packaged and the conditions under which the sterilized items are stored.

The type of contamination on a product to be sterilized varies, and this impacts upon the effectiveness of a sterilization process. Products that have been used in a health care setting, and are being presented for resterilization in accordance with the manufacturer's instructions, should be regarded as a special case. There is the potential for such products to possess a wide range of contaminating microorganisms and residual inorganic and/or organic contamination, in spite of the application of a cleaning process. Hence, particular attention is given to the validation and control of the cleaning and disinfection processes used during reprocessing.

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Sterilization technology is at several levels of development and application. There are processes which are developed and have been in use for appreciable periods, and there are processes which are being developed and introduced either for sterilization of specific products or for general application. Furthermore, there may be processes which have yet to be discovered. Experience has identified the requirements which are appropriate for existing sterilization technologies, and these requirements have been specified in International Standards specific to each established process. The intention in developing this International Standard is to use this experience to provide, for suppliers of sterilization technologies, to their users and to regulatory authorities, a knowledge of the relevant general requirements that will allow development of additional sterilization technologies to continue within a broad framework until sufficient experience, confidence and demand exist to justify the preparation of a specific International Standard.

This International Standard has three distinct applications:

— for manufacturers of health care products who wish to apply to their products a sterilization process for which a specific International Standard does not exist; and,

— for manufacturers and users of sterilization systems in health care settings for which a specific International Standard does not exist; and,

— to provide a framework for the preparation or revision of standards for specific sterilization processes.

The responsibility for carrying out the activities required by this International Standard will vary from case to case. This International Standard requires that the responsibilities of the various parties be defined (see 4.1.1) but does not specify to whom the responsibilities are allocated. Annex E provides guidance on allocation of responsibility.

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Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

1 Scope

1.1 This International Standard specifies general requirements for the characterization of a sterilizing agent, and for the development, validation and routine control of a sterilization process for medical devices.

1.2 This International Standard applies to sterilization processes in which microorganisms are inactivated by physical and/or chemical means.

1.3 This International Standard does not apply to processes that rely solely on physical removal of microorganisms (for example, filtration).

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1.4 This International Standard does not describe detailed test procedures for assessing microbial inactivation.

1.5 This International Standard is intended to be applied by process developers, manufacturers of sterilization equipment, manufacturers of medical devices to be sterilized and the organization with responsibility for sterilizing the medical device.

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1.6 This International Standard does not supersede or modify published International Standards for particular sterilization processes.

NOTE 1 Although the scope of this International Standard is limited to medical devices, the principles described may also be applied to other health care products.

NOTE 2 Sterilization processes validated and controlled in accordance with the requirements of this International Standard should not be assumed to be effective in inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeld-Jakob disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents.

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 10012-1, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment.*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing.*

ISO 10993-17, *Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances using health-based risk assessment.*

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ISO 11138-1, *Sterilization of health care products — Biological indicators — Part 1: General.*

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

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

ISO 11737-2, *Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the validation of a sterilization process.*

ISO 13485, *Quality systems — Medical devices — Particular requirements for the application of ISO 9001.*

ISO 13488, *Quality systems — Medical devices — Particular requirements for the application of ISO 9002.*

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control and laboratory use — 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 a product and/or a package

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3.2
biological indicator
microbiological test system providing a defined resistance to a specified sterilization process

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3.3
change control
formal assessment and determination of the appropriateness of a proposed alteration to product or procedure

3.4
chemical indicator
system that reveals a change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process

3.5
development
act of elaborating a specification in preparation for validation

3.6
establish
determine by theoretical evaluation and confirm by experimentation

3.7
fault
one or more of the process parameters which lies outside of its/their specified tolerance(s)

3.8
health care product
medical device, medicinal product (pharmaceuticals and biologics) or *in vitro* diagnostic medical device

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3.9
installation qualification
IQ
obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

3.10
material safety data sheet
document specifying the properties of a material, its potential hazardous effects for humans and the environment, and the precautions necessary to handle and dispose of the material safely

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 purpose 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;

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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
operational qualification
OQ

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process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

3.13
parametric release
declaration that a product is sterile, based on the records demonstrating that the process parameters were delivered within specified tolerances

3.14
performance qualification
PQ
process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification

3.15
process challenge device
item designed to simulate product to be sterilized and to constitute a defined challenge to the sterilization process, and used to assess the effective performance of the process

3.16
process parameter
specified value for a process variable

NOTE The specification for a sterilization process includes the process parameters and their tolerances.

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3.17
process variable
condition associated with a sterilization process, changes in which alter microbicidal effectiveness

NOTE Process variables may include, for example, time, temperature, pressure, concentration, humidity, wavelength.

3.18
recognized culture collection
international depository authority under the Budapest Treaty on 'The International Recognition of the Deposit of Microorganisms for the Purpose of Patent and Regulation'

3.19
reference microorganism
microbial strain obtained from a recognized culture collection

3.20
requalification
repetition of part of validation for the purpose of confirming the continued acceptability of a specified process

3.21
services
supplies from an external source, necessary for the correct functioning of sterilizing equipment

NOTE Examples of services are electricity, water, compressed air, and drainage.

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3.22
specify
stipulate in detail within an approved document

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3.23
sterile
free from viable microorganisms

3.24
sterility
state of being free from viable microorganisms

3.25
sterilization
validated process used to render a product free from viable microorganisms

3.26
sterilization load
product to be, or that has been, sterilized together using a given sterilization process

3.27
sterilization process
series of actions or operations to achieve the specified requirements for sterility

NOTE This series of actions or operations includes pre-treatment (if necessary), exposure to the sterilizing agent under defined conditions and any necessary post-treatment. It does not include any cleaning, disinfection or packaging operations that precede the sterilization process.

3.28
sterilizing agent
physical or chemical entity, or combination of entities, that have sufficient microbicidal activity to achieve sterility under defined conditions

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3.29
survivor curve
graphical representation of the inactivation of a population of microorganisms with increasing exposure to a microbicidal agent under stated conditions

3.30
test for sterility
test defined in an official Pharmacopoeia for product release following exposure to a sterilization process

3.31
test of sterility
test performed as part of development, validation or requalification to establish the presence or absence of viable microorganisms on product units, or portions thereof

3.32
validation
documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

4 Quality system elements

4.1 General

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The purpose of the quality system is to define and document procedures, the implementation of which control all stages of development, application and use of the sterilization process. It is not a requirement of this International Standard to have a complete quality system during design/development and production, but certain elements of a quality system are required and these are normatively referenced at appropriate places in the text. Attention is drawn to ISO 9001 and ISO 13485 which describe a quality system. This International Standard does not require third party assessment of the specified quality system elements.

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4.2 Assignment of responsibilities

4.2.1 The responsibility for performing each element of the procedures in this International Standard shall be defined and documented. Responsibility for each element may vary from case to case and this International Standard does not allocate responsibility for each element to particular parties.

The elements are: quality system; sterilizing agent characterization; process/equipment characterization; product definition; process definition; validation; routine monitoring and control; product release from sterilization; and maintaining process effectiveness.

NOTE These elements are illustrated in Table E.1.

4.2.2 Responsibilities shall be further assigned to qualified personnel as specified in ISO 13485 or ISO 13488.

NOTE 4.1.1, 4.1.2.2 and 4.18 of ISO 13485:1996 and ISO 13488:1996 detail requirements for management responsibility, personnel and training.

4.3 Documentation and records

4.3.1 Documented procedures for each phase of the development, validation, routine monitoring and control and product release from sterilization shall be prepared and implemented.

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