TECHNICAL SPECIFICATION

ISO/TS 22421

First edition
2021-01

Sterilization of health care products — Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities

Stérilisation des produits de santé — Exigences communes applicables aux stérilisateurs utilisés pour la stérilisation terminale des dispositifs médicaux dans les établissements de santé

Reference number
ISO/TS 22421:2021(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

A sterile health care product is one that is free of viable microorganisms. International Standards that specify requirements for validation and routine control of sterilization processes require, when it is necessary to supply a sterile health care product, that adventitious microbiological contamination of that health care product prior to sterilization be minimized. Even so, health care products produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see, for example, ISO 13485) can, prior to sterilization, have microorganisms on them, albeit in low numbers. Such health care products are non-sterile. The purpose of sterilization is to inactivate or remove the microbiological contaminants and thereby transform the non-sterile health care products into sterile ones.

Conformance with the requirements of International Standards for development, validation and routine control of sterilization processes ensures that the sterilization process is both reliable and reproducible so that predictions can be made, with reasonable confidence, that there is a low probability of there being a viable microorganism present on a health care product after sterilization.

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

a) the microbiological status of incoming raw materials or components;

b) the validation and routine control of any cleaning and disinfection procedures used on the medical device;

c) the control of the environment in which the medical device is manufactured, assembled and packaged;

d) the specified performance and maintenance of equipment;

e) the control of personnel and their hygiene;

f) the process and materials of the sterile barrier systems that are used to package the medical device;

g) the conditions under which the medical device is transported;

h) the conditions under which the medical device is stored.

The delivery of a validated and accurately controlled sterilization process is enabled by the use of sterilizing equipment that is designed, constructed, installed and qualified to deliver the sterilization process safely and reproducibly. This document defines common, general requirements that apply across a range of sterilizing equipment that can then be used:

1) as a template for future revisions of standards for sterilizing equipment for particular sterilization processes, and

2) to apply to equipment for which a particular standard does not exist.

This approach also provides opportunities not only to achieve a comprehensive and consistent set of global standards for sterilizing equipment but also to build on the work done in developing the existing standards for sterilizers at national and regional level to reach an international alignment on the requirements.

The verbal forms used in this document conform to the usage described in Clause 7 of the ISO/IEC Directives, Part 2:2018. For the purposes of this document, the auxiliary verb:

— "shall" means that conformance with a requirement or a test is mandatory for conformance with this document;

— "should" means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— "may" is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test); and

— "can" is used to express possibility and capability.

The conjunction "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The rationale for the requirements in this document has been provided in Annex A.

Sterilization of health care products — Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities

1 Scope

This document specifies the common requirements for sterilizers used for terminal sterilization of medical devices in health care facilities. This document covers sterilizers that operate with a variety of sterilizing agents (alone or in combination) within a sealed vessel at different temperatures, above, at, or below atmospheric pressure.

This document provides high-level requirements and respective test methods that are general in nature.

This document does not provide quantitative requirements for process parameters or parameters of the sterilization cycle, or requirements for performance testing, validation or routine control of sterilizers because these depend on the respective sterilization method.

This document does not supersede or modify requirements or test methods of published standards applying to sterilizers, or future editions thereof.

This document does not apply to:

— sterilizers using radiation as the sterilizing agent;

— sterilizers for laboratory equipment;

— sterilizers used to prepare culture media;

— sterilizers used for bio-decontamination of laboratory or other waste including decontamination of pathogens in a high risk category;

— systems used for bio-decontamination of rooms and isolator systems;

— systems used for sterilization in place; or

— washer-disinfectors.

NOTE Whilst this document provides requirements for sterilizers used in health care applications, there will be elements that are applicable to industrial applications.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 3746, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane*

ISO 8573-1, *Compressed air — Part 1: Contaminants and purity classes*

ISO 14937:2009, *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*

ISO 20417, *Medical devices — Information to be provided by the manufacturer*

IEC 61010-2-040, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*

IEC 61326-1, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
access device
means by which entry to restricted parts of equipment is achieved

Note 1 to entry: This can be by dedicated key, code, or tool.

[SOURCE: ISO 11139:2018, 3.4]

3.2
accompanying information
information accompanying or marked on a sterilizer and containing information for the user or those accountable for the installation, use, maintenance, decommissioning and disposal of the sterilizer, particularly regarding safe use

Note 1 to entry: The accompanying information can be regarded as part of the sterilizer.

Note 2 to entry: The accompanying information can consist of the label (see 3.29), marking, instructions for use, technical description, installation manual, quick reference guide, etc.

Note 3 to entry: Accompanying information is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g. CD/DVD-ROM, USB stick, website).

[SOURCE: ISO 20417:2021, 3.2, modified — "Medical device or accessory" has been changed to "sterilizer", the term "processing" has been removed, Note 1 to entry has been modified to exclude a requirement and Note 4 to entry has been deleted.]

3.3
automatic controller
device that directs the equipment sequentially through required stages of the cycle in response to programmed *cycle parameters* (3.12)

[SOURCE: ISO 11139:2018, 3.18]

3.4
bio-decontamination
removal and/or reduction of biological contaminants to an acceptable level

[SOURCE: ISO 11139:2018, 3.27]

3.5
biological indicator
test system containing viable microorganisms providing a specified resistance to a specified *sterilization process* (3.66)

[SOURCE: ISO 11139:2018, 3.29]

3.6
calibration
operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

[SOURCE: ISO 11139:2018, 3.31]

3.7
chamber
part of equipment in which a load is processed

[SOURCE: ISO 11139:2018, 3.36]

3.8
chemical indicator
test system that reveals change in one or more pre-specified *process variables* (3.50) based on a chemical or physical change resulting from exposure to a process

[SOURCE: ISO 11139:2018, 3.43]

3.9
cleaning
removal of contaminants to the extent necessary for further processing or for intended use

[SOURCE: ISO 11139:2018, 3.46]

3.10
control
regulation of variables within specified limits

[SOURCE: ISO 11139:2018, 3.63]

3.11
cycle complete
message from the automatic controller that the operating cycle has ended successfully

[SOURCE: ISO 11139:2018, 3.71]

3.12
cycle parameter
value of a *cycle variable* (3.13) including its tolerance used for *control* (3.10), *monitoring* (3.39), indication, and recording of an operating cycle

[SOURCE: ISO 11139:2018, 3.72]

3.13
cycle variable
property used to *control* (3.10), monitor, indicate, or record an *operating cycle* (3.42)

[SOURCE: ISO 11139:2018, 3.74]

3.14
desorption
removal of the *sterilizing agent* (3.68) from the *chamber* (3.7) and the load at the end of the *exposure phase* (3.17)

[SOURCE: ISO 11139:2018, 3.78]

3.15
double-ended
having separate doors for loading and unloading in separate areas

[SOURCE: ISO 11139:2018, 3.92]

3.16
equipment maintenance
combination of all technical and associated administrative actions intended to keep equipment at a state in which it can perform its required function, or restore it to such a state

[SOURCE: ISO 11139:2018, 3.106]

3.17
exposure phase
cycle stage between the introduction of the sterilizing or disinfecting agent into the *chamber* (3.7) and when the agent is removed

[SOURCE: ISO 11139:2018, 3.111]

3.18
fault
situation in which one or more of the process or *cycle parameters* (3.12) is/are outside its/their specified tolerance(s)

[SOURCE: ISO 11139:2018, 3.116]

3.19
filter
construct of porous material through which a *fluid* (3.20) is passed to remove viable and/or non-viable particles

[SOURCE: ISO 11139:2018, 3.117]

3.20
fluid
substance that continually deforms (flows) under applied shear force

EXAMPLE Liquid, gas, vapour, plasma.

[SOURCE: ISO 11139:2018, 3.120]

3.21
hazard
potential source of harm

[SOURCE: ISO 11139:2018, 3.130]

3.22
hazardous situation
circumstance in which people, property, or the environment is/are exposed to one or more *hazards* (3.21)

[SOURCE: ISO 11139:2018, 3.131]

3.23
health care product
medical device (3.36), including in vitro diagnostic medical device, or medicinal product, including biopharmaceutical

[SOURCE: ISO 11139:2018, 3.132]

3.24
humidity
measure of water vapour present in a gas

Note 1 to entry: Humidity is usually expressed as absolute humidity (i.e. vapour pressure density), relative humidity, or dew point.

[SOURCE: ISO 11139:2018, 3.136]

3.25
indicate
display a value, condition, or stage of process

[SOURCE: ISO 11139:2018, 3.139]

3.26
information supplied by the manufacturer
all information related to the identification and use of a sterilizer, in whatever form provided, intended to ensure the safe and effective use of the *sterilizer* (3.67)

Note 1 to entry: For the purposes of this document, shipping documents and promotional material are excluded from information supplied by the manufacturer. However, some authorities having jurisdiction can consider such supplemental information as information supplied by the manufacturer.

[SOURCE: ISO 20417:2021, 3.10, modified — "Medical device or accessory" has been changed to "sterilizer" and Notes 1, 3 and 4 to entry have been deleted.]

3.27
installation qualification
IQ
process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation comply with the approved specification

[SOURCE: ISO 11139:2018, 3.220.2]

3.28
instructions for use
IFU
portion of the *accompanying information* (3.2) that is essential for the safe and effective intended use of a *sterilizer* (3.67) directed to the user of the sterilizer

Note 1 to entry: The instructions for use, or portions thereof, can be located on the display of a sterilizer.

[SOURCE: ISO 20417:2021, 3.11, modified — "Medical device or accessory" has been changed to "sterilizer", "package insert" has been removed, "use" has been changed to "intended use", Notes 1, 2, 4 and 5 to entry have been deleted and Note 3 to entry has been modified.]

3.29
label
written, printed, or graphic information appearing on the *sterilizer* (3.67) itself

Note 1 to entry: Label includes the marking on the sterilizer.

[SOURCE: ISO 20417:2021, 3.12, modified — The term "item" has been replaced with "sterilizer", reference to packaging and provision of multiple items has been deleted, Notes 1 and 3 to entry have been deleted, and Note 2 to entry has been designated as Note 1.]

3.30
load
product, equipment, or materials to be processed together within an *operating cycle* (3.42)

[SOURCE: ISO 11139:2018, 3.155]

3.31
load configuration
distribution and orientation of a *load* (3.30)

[SOURCE: ISO 11139:2018, 3.156]

3.32
loading door
means of access through which a *load* (3.30) is passed into the chamber before processing

[SOURCE: ISO 11139:2018, 3.157]

3.33
marking
information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a *sterilizer* (3.67)

Note 1 to entry: For the purposes of this document, the term *marked* is used to designate the corresponding act.

Note 2 to entry: For the purposes of this document, marking is different from "direct marking" as described in systems for unique device identification (UDI) of medical devices.

[SOURCE: ISO 20417:2021, 3.16, modified — "Medical device or accessory" has been changed to "sterilizer". Note 2 to entry has been modified. Note 3 to entry has been deleted.]

3.34
measurement uncertainty
non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

[SOURCE: ISO 11139:2018, 3.164]

3.35
measuring chain
series of elements of a measuring instrument or measuring system, which constitutes the path of the measurement signal from the input (quantity subject to measurement) to the output (the result of the measurement)

[SOURCE: ISO 11139:2018, 3.165]

3.36
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, or software material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

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

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

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

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information by means of *in vitro* examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means

