SLOVENSKI STANDARD
SIST EN ISO 11139:2018/oprA1:2023

01-maj-2023

Sterilizacija izdelkov za zdravstveno nego - Slovar izrazov, ki se uporabljajo pri sterilizaciji in ustrezni opremi ter pri procesnih standardih - Dopolnilo A1: Spremenjeni in dodatni izrazi in definicije (ISO 11139:2018/DAM 1:2023)

Sterilization of health care products - Vocabulary of terms used in sterilization and related equipment and process standards - Amendment 1: Amended and additional terms and definition (ISO 11139:2018/DAM 1:2023)

Sterilisation von Produkten für die Gesundheitsfürsorge - Vokabular, das bei der Sterilisation und zugehöriger Ausrüstung sowie in Prozessnormen verwendet wird - Änderung 1 (ISO 11139:2018/DAM 1:2023)

Stérilisation des produits de santé - Vocabulaire des termes utilisés dans les normes de procédés de stérilisation et les équipements connexes - Amendement 1: Termes et définitions modifiés et supplémentaire (ISO 11139:2018/DAM 1:2023)

Ta slovenski standard je istoveten z: **EN ISO 11139:2018/prA1**

ICS:

01.040.11	Zdravstveno varstvo (Slovarji)	Health care technology (Vocabularies)
11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

SIST EN ISO 11139:2018/oprA1:2023 **en,fr,de**

DRAFT AMENDMENT
ISO 11139:2018/DAM 1

ISO/TC **198** Secretariat: **ANSI**

Voting begins on: **2023-03-07**

Voting terminates on: **2023-05-30**

Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards

AMENDMENT 1: Amended and additional terms and definition

ICS: 11.080.01; 01.040.11

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO 11139:2018/DAM 1:2023(E)

COPYRIGHT PROTECTED DOCUMENT

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

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.

Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards

AMENDMENT 1: Amended and additional terms and definition

3.111

Replace the term and the text of the definition with the following:

3.111
exposure stage
cycle stage between the introduction of the sterilizing agent or disinfecting agent into the chamber and when the agent is removed or neutralised

3.113.2

Delete 3.113.2 and renumber 3.113.3 to 3.113.2.

3.133

Replace the text of the definition with the following:

3.133
holding time
period during which process or cycle parameters are maintained, within their specified tolerances for defined cycle stages

3.151

Replace the text of the definition with the following:

3.151
labelling
label, instructions for use and any other information related to identification, technical description, intended purpose, and proper use of the medical device, but excluding shipping documents

[SOURCE: ISO 13485:2016, 3.8]

3.166

Replace the text of the definition with the following:

3.166
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, in or on the human body, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions, but not in others include:

— items specifically intended for cleaning or sterilization of medical devices;

— pouches, reel goods, sterilization wrap, and reusable containers for packaging of medical devices for sterilization;

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for *in vitro* fertilization or assisted reproduction technologies.

[SOURCE: ISO 13485:2016, 3.11, modified — “In or on the human body” has been added to the definition and the first two list items in Note 1 to entry have been added]

3.214

Renumber as follows:

3.214.2
processing
<preparation of medical devices> activity to prepare a new or used health care product for its intended use

3.230

Delete.

3.231

Delete.

3.254

Replace the text of the definition with the following:

3.254
simulated product
item intended to represent specified characteristics of a product or product family used to demonstrate a defined performance of a process related to these characteristics

3.293.1

Replace the text of the definition with the following:

3.293.1
temperature band
<operating> range of temperatures expressed as the minimum and maximum temperatures in the usable chamber space during a holding time

Note 1 to entry: An operating cycle can comprise more than one holding time

3.296

Replace the text of the definition with the following:

3.296
terminally sterilized
exposed to a successful sterilization process in its sterile barrier system

Clause 3

Add the following:

3.133.1
holding time
<moist heat sterilization> period for which the temperatures at the reference measurement point and at all points within the load are continuously within the sterilization temperature band

3.214.1
processing
<*biologics* and *tissue-based product*> activity performed in the preparation, manipulation, preservation for storage and packaging of a biological or tissue-based product

3.328
acceptance range
<irradiation> range within which the statistic under consideration lies with a specified probability when the process is in a state of control

3.329
accompanying information
information accompanying or marked on a medical device or accessory and containing information for the user or those accountable for the installation, use, maintenance, decommissioning and disposal of the medical device or accessory, particularly regarding safe use

Note 1 to entry: The accompanying information can be regarded as part of the medical device or accessory.

Note 2 to entry: The accompanying information can consist of the label, 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).

Note 4 to entry: The label can include the information on the packaging of the medical device.

Note 5 to entry: E-documentation can include any or all types of information supplied by the manufacturer partially or entirely.

Note 6 to entry: Marketing information is also known as promotional material.

[SOURCE: ISO 20417:2021, 3.2, modified — the term "processing" has been removed, Note 1 to entry has been modified to exclude a requirement, Note 4 to entry has been deleted, and Notes 5 to 7 have been renumbered 4 to 6]

3.330
biologic
product that is synthesized from living organisms, or their products, and used as a diagnostic, preventive or therapeutic agent

3.331
companion tissue
tissue from the same donor(s) that is not intended to be used for transplantation

3.332
contained product sterilization
validated process where indirect contact of a heating medium on the external surfaces of contained product to create moist heat internally to achieve the specified requirements for sterility within the contained product

3.333
critical medical device
<washer-disinfector> item, processed in a washer-disinfector, intended to be introduced directly into, or have contact with, the vascular system or normally sterile areas of the body

EXAMPLE Surgical instruments.

Note 1 to entry: Critical medical devices will usually require sterilization before use

Note 2 to entry: There can be national regulations with alternative wording for this term

3.334
donor identification
unique identifier assigned to all transplantable tissue and companion tissue that originates from the same donor

3.335
end product testing
testing carried out on product samples that have completed the entire manufacturing process

3.336
endotoxin limit
maximum allowable level of endotoxin specified for a product