SLOVENSKI STANDARD
oSIST prEN ISO 11139:2017

01-oktober-2017

Sterilizacija izdelkov za zdravstveno nego - Slovar - Izrazi, ki se uporabljajo pri sterilizaciji in ustrezni opremi ter pri procesnih standardih (ISO/DIS 11139:2017)

Sterilization of health care products - Vocabulary - Terms used in sterilization and related equipment and process standards (ISO/DIS 11139:2017)

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Sterilisation von Produkten für die Gesundheitsfürsorge - Vokabular -Begriffe, die bei der Sterilisation und zugehörigen Geräten sowie in Prozessnormen verwendet werden (ISO/DIS 11139:2017)

SIST EN ISO 11139:2018

Stérilisation des produits de santé - Vocabulaire (ISO/DIS 11139:2017)

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Ta slovenski standard je istoveten z: **prEN ISO 11139**

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ISO /TC 198

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ISO/TC 198/WG 5

Secretariat: AAMI (for ANSI)

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

Stérilisation des produits de santé — Vocabulaire

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This document was prepared by Technical Committees ISO/TC 198, *Sterilization of healthcare products* and CEN/TC102 *Sterilizers and associated equipment for processing of medical devices*.

This second edition cancels and replaces the first edition ISO/TS 11139:2006, which has been technically and editorially modified and expanded to include additional terms.

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Introduction

There are of the order of 80 standards in the sterilization and associated areas in the ISO and EN series. Most of these standards use terms that are used in other standards. ISO/TS 11139 was published in 2006 with a selected list of common terms used in the field. The current version of the Vocabulary standard has extended its scope to cover all the terms used in each of the current standards, their revisions in process, and new draft standards. By this means, authors of new standards will be able to identify terms already in use, and therefore reduce the risk of the same term or abbreviation being used in a different way.

Under each definition the standards in which the term has been used is referenced. However, the terms in this document have many instances where the definitions have been updated from the originally published definitions, and it is expected that the definitions used in individual existing standards will be updated as each standard is revised. Where a term has been used already in more than one standard it has required the different ISO and CEN Working Groups employing the same term to agree on a common definition. There are also instances where the term has been modified as well.

Some terms that have been listed in existing standards, but that are in common usage and in standard dictionaries have been recommended that they do not need a definition in a sterilization standard: these terms have been listed in Annex A with the reason for exclusion indicated.

In a Vocabulary standard there are some general rules that have been applied to terms in this International Standard where they have been used in more than one of the reviewed standards, and authors of new standards are asked to review their definitions to ensure that these general rules are followed. For example there should be no requirements included in the definition. The words in the term should ideally not be repeated in the definition, nor should the definition be circular (e.g. Air Removal: removal of air).

The membership of the Working Group working on this International Standard has included the Convenors of the ISO TC198 “*Sterilization of healthcare products*”, CEN TC204 “*Sterilization of medical devices*”, and CEN TC102 “*Sterilizers and associated equipment for processing of medical devices*” Working Groups.

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

1 Scope

This International Standard defines terms in the field of sterilization of healthcare products used in the standards developed by ISO TC198 *"Sterilization of healthcare products"*, CEN TC204 "*Sterilization of medical devices"*, and CEN TC102 "*Sterilizers and associated equipment for processing of medical devices"*.

2 Normative references

There are no normative references in this document.

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 http://www.iso.org/obp

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

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3.1
A_0
measure of microbiological lethality delivered by a moist heat disinfection process expressed in terms of the equivalent time in seconds at 80 °C with reference to a microorganism with a *z* value of 10 K

[Term used in: ISO 15883-1:2009 + A1:2014; ISO15883-2:2009; ISO15883-3:2009]

3.2
absolute pressure
pressure for which the zero value is associated with absolute vacuum

[Term used in: EN 285:2015; EN 764-1:2004]

3.3
absorbed dose
quantity of ionizing radiation energy imparted per unit mass of a specified material

[Term used in: ISO 11137-1:2015; ISO/TS 13004:2014]

3.4
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

[Term used in: EN 285:2015; EN 14180:2014]

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3.5
action level
value from monitoring that necessitates immediate intervention

[Term used in: ISO 13408-1:2015]

3.6
active ingredient
chemical or biological component that is included in the formulation of a healthcare product in sufficient concentration to achieve the intended therapeutic purpose of the specific product

[Term used in: ISO 18362:2016]

3.7
aeration
part of the sterilization cycle during which the sterilizing agent and/or its reaction products desorb from the medical device until predetermined levels are reached

[Term used in: EN 1422:2014; EN 14180:2014; ISO 11135:2014; ISO/DIS 25424:2017]

3.8
air break
physical separation in water supply pipes to prevent back flow from equipment

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[Term used in: ISO/DIS 15883-4:2016]

3.9
air detector
device designed to detect the presence of non-condensable gases in the chamber or in a stream of steam and condensate

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[Term used in: ISO 17665-1:2006]

3.10
airlock
enclosure with interlocked doors designed to maintain pressure control between adjacent areas

[Term used in: ISO 13408-1:2015]

3.11
alert level
value from monitoring providing early warning of deviation from specified conditions

[Term used in: ISO 13408-1:2015]

3.12
analyte
chemical substance that is the subject of chemical analysis

[Term used in: ISO/FDIS 15883-4:2017; ISO/CD 15883-5:2017]

3.13
aseptic presentation
transfer of sterile product using conditions and procedures that minimise the risk of microbial contamination

[Term used in: ISO/DIS 11607-1:2017]

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3.14
aseptic processing
handling of sterile product, containers, and/or devices in a controlled environment in which the air supply, materials, equipment and personnel are regulated to maintain sterility

[Term used in: EN 556-2:2015; ISO 13408-1:2015]

3.15
aseptic processing area
APA
facilities for aseptic processing, consisting of several zones

[Term used in: 13408-1:2015]

3.16
aseptic technique
conditions and procedures used to minimise the risk of the introduction of microbial contamination

[Term used in: ISO/DIS 11138-7:2017; ISO 13408-1:2015; ISO 18362:2016]

3.17
assurance of sterility
qualitative concept comprising all activities that provide confidence that product is sterile

[Term used in: ISO/TS 19930:2017]

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3.18
automatic controller
device that directs the equipment sequentially through required stages of the cycle in response to programmed cycle parameters

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[Term used in: EN 285:2015; EN 1422:2014; EN 13060:2014; EN 14180:2014; ISO 15883-1:2009 + A1:2014; ISO 17665-1:2006]

3.19
bacterial challenge test
<aseptic processing> technical operation performed to evaluate the capability of a filter to retain organisms from a liquid bacterial suspension under defined conditions

[Term used in: ISO/CD 13408-2:2016]

3.20
bacteriostasis/fungistasis test
technical operation performed to detect the presence of substances that inhibit microbial multiplication

[Term used in: ISO 11737-2:2009]

3.21
batch
defined quantity of product intended or purported to be uniform in character and quality, which has been produced during a defined cycle of manufacture

[Term used in: ISO 11137-2:2015; ISO/FDIS 11737:2017; ISO/TS 13004:2014; ISO 14160:2011; ISO 20857:2013]

3.22
bedpan washer-disinfector
washer-disinfector for human waste containers that additionally empties and flushes

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[Term used in: ISO 15883-1:2009 + A1:2014]

3.23
bioburden
population of viable microorganisms on or in product and/or sterile barrier system

[Term used in: EN 556-1:2001; EN 556-2:2015; ISO 11135:2014; ISO 11137-1:2015; ISO 11137-2:2015; ISO/DIS 11138-7:2017; ISO/DIS 11607-1:2017; ISO/FDIS 11737:2017; ISO 11737-2:2009; ISO/TS 13004:2014; ISO 13408-1:2015; ISO/CD 13408-2:2016; ISO 14160:2011; ISO 14937:2009; ISO 15883-1:2009 + A1:2014; ISO 17665-1:2006; ISO/TS 19930:2017; ISO 20857:2013; ISO/DIS 25424:2017]

3.24
bioburden correction factor
numerical value applied to a viable count to compensate for incomplete removal of microorganisms from product and/or failure to culture of microorganisms

[Term used in: ISO/FDIS 11737:2017]

3.25
bioburden estimate
value established by applying a correction factor to a bioburden count

[Term used in: ISO/FDIS 11737:2017]

3.26
bioburden spike
an individual bioburden value that is significantly greater than other bioburden values in a set

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[Term used in: ISO/FDIS 11737:2017]

3.27
bio-decontamination
removal and/or reduction of biological contaminants to an acceptable level

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[Term used in: ISO 13408-1:2015; ISO 13408-6:2011 + A1:2013]

3.28
biological contaminant
cell or biological entity other than the intended components present in product

EXAMPLE: Viruses, bacteria, fungi, protozoa, multicellular parasites, contaminating eukaryotic cells, aberrant proteins known as prions, endotoxins, or active DNA/RNA

Note 1 to entry: This can include extrinsic and/or intrinsic contaminants.

Note 2 to entry: A biological entity is a functional assembly of biological molecules or structures, and could be an enzyme complex, a membranous structure, ribosomes, etc, or a combination thereof that is kept assembled to maintain its biological functionality.

[Term used in: ISO 18362:2016]

3.29
biological indicator
test system containing viable microorganisms providing a defined resistance to a specified sterilization process

[Term used in: EN 1422:2014; EN 13060:2014; EN 14180:2014; ISO 11135:2014; ISO 11137-1:2015; ISO 11138-1:2017; ISO/DIS 11138-7:2017; ISO/CD 11138-8:2015; ISO 14937:2009; ISO 17665-1:2006; ; ISO/FDIS 18472:2017; ISO/TS 19930:2017; ISO 20857:2013; ISO/DIS 25424:2017]

3.30

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block
<endoscope> group of channels comprising part of an endoscope with specified lengths, diameters and interconnections

[Term used in: ISO/DIS 15883-4:2016]

3.31
calibration
operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by the 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: VIM:2012]

[Term used in: EN 1422:2014; EN 13060:2014; ISO 11135:2014; ISO 11137-1:2015; ISO 15883-1:2009 + A1:2014; ISO 17665-1:2006; ISO/FDIS 18472:2017; ISO 20857:2013; ISO/DIS 25424:2017]

3.32
calorifier
closed vessel, at a pressure greater than atmospheric, in which water is indirectly heated by the flow of heated fluid through a heat exchanger

[Term used in: ISO 15883-1:2009 + A1:2014]

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3.33
carrier
<biological indicator> supporting material on or in which test microorganisms are deposited

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[Term used in: ISO 11138-1:2017; ISO/CD 11138-8:2015; ISO 14160:2011]

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3.34
cell-based
containing or consisting of pro- or eukaryotic cells or cell derived biological entities

[Term used in: ISO 18362:2016]

3.35
cell-processing area
CPA
area for processing cell-based materials consisting of different zones for processing and, where applicable, for containment

[Term used in: ISO 18362:2016]

3.36
chamber
part of equipment in which a load is processed

[Term used in: EN 285:2015; EN 13060:2014; EN 14180:2014; ISO 15883-1:2009 + A1:2014; ISO 17665-1:2006]

3.37
chamber pre-heating
raising the temperature of internal chamber surfaces prior to the commencement of an operating cycle

[Term used in: EN 14180:2014]

3.38
chamber reference temperature

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temperature at a defined point within the chamber

[Term used in: ISO 11140-4:2007]

3.39
change control
assessment and determination of the appropriateness of a proposed alteration to product, process or equipment

[Term used in: ISO 11137-1:2015; ISO 14937:2009; ISO/TS 19930:2017; ISO 20857:2013; ISO/DIS 25424:2017]

3.40
channel separator
<endoscope> device that is used to keep apart interconnected fluid pathways

Note 1 to entry: For example, a device inserted in a trumpet valve cylinder where multiple channels meet in order to separate the air and water pathways in the air/water valve assembly

[Term used in: ISO/DIS 15883-4:2016]

3.41
chemical compatibility (filter)
capability of process fluids and filter materials to be used together, under the specified process conditions, without adverse effects on either the fluids or filter materials

[Term used in: ISO/CD 13408-2:2016]

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3.42
chemical disinfection
removal or reduction of microorganisms achieved by the action of one or more chemicals

[Term used in: ISO 15883-1:2009 + A1:2014]

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3.43
chemical indicator
test system that reveals change in one or more pre-defined process variables based on a chemical or physical change resulting from exposure to a process

[Term used in: EN 13060:2014; ISO 11135:2014; ISO 11140-1:2014; ISO 11140-5:2007; ISO 14937:2009; ISO 15882:2008; ISO 17665-1:2006; ISO/FDIS 18472:2017:2016; ISO/TS 19930:2017; ISO 20857:2013; ISO/DIS 25424:2017]

3.44
chemical indicator endpoint
completion of a defined change after a chemical indicator has been exposed to specified conditions

[Term used in: ISO 11140-1:2014; ISO 15882:2008]

3.45
clean
visually free of soil and quantified as being below specified levels of analytes

[Term used in: ISO/CD 15883-5:2017]

3.46
cleaning
removal of contaminants to the extent necessary for further processing or for intended use

[Term used in: ISO 13408-1:2015; ISO 15883-1:2009 + A1:2014; ISO/FDIS 17664-1:2017]

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3.47
cleaning agent
physical or chemical entity, or combination of entities, having sufficient activity to render an item clean

[Term used in: ISO 13408-4:2011]

3.48
clean-in-place
CIP
cleaning of internal surfaces of parts of equipment or an entire process system, without or with minimal, disassembly

[Term used in: ISO 13408-4:2011]

3.49
clinical use
use of a medical device during a procedure on a patient

[Term used in: ISO/CD 15883.5:2017]

3.50
closed system
means to prevent egress of hazardous agents and ingress of extrinsic contamination

[Term used in: ISO 18362:2016]

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3.51
closure integrity
characteristic of the closure to minimize the risk of ingress of microorganisms demonstrated under test conditions which consider sterilization process, handling, distribution, transport and storage

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[Term used in: ISO/DIS 11607-1:2017]

3.52
colony forming unit
CFU
visible unit of growth of microorganisms arising from a single cell or multiple cells

[Term used in: ISO 11138-1:2017; ISO/DIS 15883-4:2016]

3.53
combination product
entity presented as a single healthcare product that physically, chemically or otherwise brings together or mixes items regulated under separate legislation

Note 1 to entry: The entity might be a combination of medical device and medicinal product or biopharmaceutical.

[Term used in: ISO 13408-1:2015]

3.54
combined standard measurement uncertainty
standard measurement uncertainty that is obtained using the individual standard measurement uncertainties associated with the input quantities in a measurement model.

[SOURCE: VIM:2012]

[Term used in: ISO 11137-3:2017]

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