SLOVENSKI STANDARD
SIST EN ISO 11139:2018

01-december-2018

Sterilizacija izdelkov za zdravstveno nego - Slovar izrazov, ki se uporabljajo pri sterilizaciji in ustrezni opremi ter pri procesnih standardih (ISO 11139:2018)

Sterilization of health care products - Vocabulary of terms used in sterilization and related equipment and process standards (ISO 11139:2018)

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

Stérilisation des produits de santé - Vocabulaire des termes utilisés dans les normes de procédés de stérilisation et les équipements connexes (ISO 11139:2018)

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

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 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11139

September 2018

ICS 01.040.11; 11.080.01

English Version

Sterilization of health care products - Vocabulary of terms used in sterilization and related equipment and process standards (ISO 11139:2018)

Stérilisation des produits de santé - Vocabulaire des termes utilisés dans les normes de procédés de stérilisation et les équipements connexes (ISO 11139:2018)

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This European Standard was approved by CEN on 1 September 2018.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 11139:2018) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2019, and conflicting national standards shall be withdrawn at the latest by March 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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ISO 11139 mentions a „White Paper“ in the ISO Foreword. CEN does not endorse this „White Paper“ for the following reasons:

— there was no official standardisation request for the preparation of such a document,

— the document has not been developed according to CEN Internal Regulations and

— the document is outside the scope of EN ISO 11139.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11139:2018 has been approved by CEN as EN ISO 11139:2018 without any modification.

INTERNATIONAL STANDARD

ISO 11139

First edition
2018-08

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

Stérilisation des produits de santé — Vocabulaire des termes utilisés dans les normes de procédés de stérilisation et les équipements connexes

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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.

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).

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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 the following URL: www.iso.org/iso/foreword.html.

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

This first edition of ISO 11139 cancels and replaces ISO/TS 11139:2006, which has been technically revised.

The main changes compared with the previous edition are as follows:

— all the terms and definitions have been reviewed based on existing documents in the field and future needs, and have been revised accordingly for consistency of use;

NOTE This vocabulary is now the source document for these terms.

— additional terms and definitions have been added.

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

This document provides the fundamental vocabulary for sterilization of health care products and associated equipment. It provides the foundation for other standards on cleaning, disinfecting, sterilizing, and aseptic processing of health care products together with associated equipment and ancillary products used in ensuring effective application of these processes. This document is intended to help the user to understand the vocabulary of cleaning, disinfecting, sterilizing, and aseptically processing health care products, in order to be able to implement the related standards effectively.

This document contains the terms and definitions that apply to all standards on cleaning, disinfecting, sterilizing, and aseptic processing of health care products together with associated equipment and ancillary products developed by ISO/TC 198 and other European standards in the same field of application.

The terms and definitions are arranged in alphabetical order in English.

ISO/TC 198 has produced a white paper describing the principles used to develop this compilation of terms and definitions and proposals on its use in the development of new and revised standards for disinfecting, sterilizing, and aseptic processing of health care products together with associated equipment and ancillary products. This white paper is available through the International Organization for Standardization.

The Bibliography includes the standards referenced in Annex A. If a term has been dropped in a current revision, reference has not been made.

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

1 Scope

This document defines terms in the field of the sterilization of health care products including related equipment and processes.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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
***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

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

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

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.

3.5
action level
value from monitoring that necessitates immediate intervention

3.6
active ingredient
chemical or biological component that is included in the formulation of a health care product to achieve the intended purpose

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

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

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

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

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

3.12
analyte
chemical substance that is the subject of chemical analysis

3.13
aseptic presentation
transfer of sterile contents from its sterile barrier system using conditions and procedures that minimize the risk of microbial contamination

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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

3.30
block
<endoscope> group of channels comprising part of an endoscope with specified lengths, diameters, and interconnections

3.31
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/IEC Guide 99:2007, 2.39, modified — The notes to entry have been deleted.]