

# SVENSK STANDARD

## SS-EN ISO 11139:2018



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**Sterilisering av medicintekniska produkter – Terminologi  
– Termer som används i standarder för sterilisering samt  
tillhörande utrustning och processer (ISO 11139:2018)**

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

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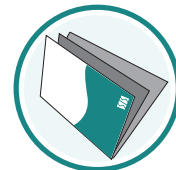
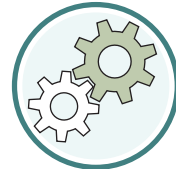
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Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på [www.sis.se](https://www.sis.se) - där hittar du mer information.



EUROPEAN STANDARD

EN ISO 11139

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2018

ICS 01.040.11; 11.080.01

English Version

## Sterilization of health care products - Vocabulary - 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)

Sterilisation von Produkten für die  
Gesundheitsfürsorge - Vokabular -Begriffe, die bei  
der Sterilisation und zugehörigen Geräten sowie in  
Prozessnormen verwendet werden (ISO 11139:2018)

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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 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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### Endorsement notice

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

## 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

## SS-EN ISO 11139:2018 (E)

### 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.]

**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