



BSI Standards Publication

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

National foreword

This British Standard is the UK implementation of EN ISO 11139:2018+A1:2024, incorporating corrigendum September 2018. It is identical to ISO 11139:2018, incorporating amendment 1:2024. It supersedes [BS EN ISO 11139:2018](#), which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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© The British Standards Institution 2024
Published by BSI Standards Limited 2024

ISBN 978 0 539 18576 8

ICS 01.040.11; 11.080.01

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 September 2018.

Amendments/corrigenda issued since publication

Date	Text affected
31 October 2018	Implementation of CEN correction notice 26 September 2018: European foreword replaced
31 January 2024	Implementation of ISO amendment 1:2024 with CEN endorsement A1:2024. Corrections to National foreword and front cover corrigendum date

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11139:2018
+A1

January 2024

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)

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

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

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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.

According to CEN Internal Regulations, terms and definition are always developed for a specific subject of the relevant standard/specification of the relevant working group. The working group uses the advice of the terminology working group to ensure that new terms and definitions are in line with the regulations and not in conflict with existing terms and definitions. Whenever possible, terms and definitions can be taken from the terminology standard [EN ISO 11139](#).

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.

European foreword to amendment A1

This document (EN ISO 11139:2018/A1:2024) 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 Amendment to the European Standard [EN ISO 11139:2018](#) shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2024, and conflicting national standards shall be withdrawn at the latest by July 2024.

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Endorsement notice

The text of ISO 11139:2018/Amd 1:2024 has been approved by CEN as EN ISO 11139:2018/A1:2024 without any modification.

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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).

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 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.]

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

3.33

carrier

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

3.34

cell-based

containing or consisting of prokaryotic or eukaryotic cells or cell derived biological entities

Note 1 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.

3.35

cell-processing area

CPA

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

3.36

chamber

part of equipment in which a load is processed

3.37

chamber pre-heating

process that raises the temperature of internal chamber surfaces prior to the commencement of an operating cycle

3.38

chamber reference temperature

temperature at a specified point within the chamber

3.39

change control

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

3.40

channel separator

<endoscope> device used to keep apart interconnected fluid pathways

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.

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

3.42

chemical disinfection

disinfection achieved by the action of one or more chemicals

3.43

chemical indicator

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

3.43.1

chemical indicator system

combination of a chemical indicator and a specific test load

3.44

chemical indicator endpoint

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

3.45

clean

visually free of soil and below specified levels of analytes

3.46

cleaning

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

3.47

cleaning agent

physical or chemical entity, or combination of entities, having activity to render an item clean

3.48

clean-in-place

CIP

cleaning of internal surfaces of parts of equipment or an entire process system, without or with minimal, disassembly

3.49

clinical use

use of a health care product during a procedure on a patient

3.50

closed system

<aseptic processing> means to prevent egress of hazardous agents and ingress of extrinsic contamination

3.51

closure

<packaging> means used to complete a sterile barrier system where no seal is formed

3.52

closure integrity

<packaging> characteristics of a closure to minimize the risk of ingress of microorganisms

3.53

colony forming unit

CFU

visible aggregation of microorganisms arising from a single cell or multiple cells

3.54

combination product

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

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

3.55

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: ISO/IEC Guide 99:2007, 2.31, modified — The admitted term and the Note 1 to entry have been deleted.]

3.56

come-down period

<resistometer> time elapsed from the termination of the exposure period to an established null reaction point

3.57

come-up period

<resistometer> time elapsed from the introduction of the sterilizing agent to the attainment of the specified conditions

3.58

conditioning

treatment of product prior to the exposure phase to attain a specified temperature, relative humidity, or other process variable throughout the load

3.59

containment

combination of buildings, engineering functions, equipment, and work practices that allow safe handling of hazardous biological or chemical substances, and prevent accidental release of these substances to the external environment

3.60

containment area

designated location consisting of a cell processing area and an associated degowning room

3.61

containment facility

combination of manufacturing rooms including the containment area and associated rooms within a physical containment barrier

Note 1 to entry: This can include airlocks, access and support rooms, laboratories, and interconnecting corridors.

Note 2 to entry: A containment facility uses a series of barriers (primary, secondary, and tertiary) to minimize the escape of hazardous agents to facility workers, the general population, and the environment, e.g. isolators (if necessary, negative pressure type); biological safety cabinets (Class I, II or III); negative air pressure cleanroom; personnel protective clothing; appropriate work practices; appropriate disposal of hazardous waste; restriction of access to the facility.

3.62

continuous process machine

equipment that moves one work unit at a time between each step of the process with the product generally remaining in motion

Note 1 to entry: This is contrasted with batch process equipment, which would expose the entire batch to each step of the process, one step at a time.

3.63

control

regulation of variables within specified limits

3.64

correction

action to eliminate a detected nonconformity

Note 1 to entry: A correction can be made in advance of, in conjunction with, or after a corrective action.

[SOURCE: ISO 9000:2015, 3.12.3, modified — The Note 2 to entry has been deleted.]

3.65

corrective action

action to eliminate the cause of a nonconformity and to prevent recurrence

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

[SOURCE: ISO 9000:2015, 3.12.2, modified – Note 3 to entry has been deleted]

3.66

coverage factor

number larger than one by which a combined standard measurement uncertainty is multiplied to obtain an expanded measurement uncertainty

Note 1 to entry: A coverage factor is usually symbolized *k*.

[SOURCE: ISO/IEC Guide 99:2007, 2.38]

3.67

critical processing zone

location within the aseptic processing area in which product and critical surfaces are exposed to the environment

3.68

critical surface

surface that might come into direct contact with a product, including its containers or closures, posing a risk of contamination

3.69

culture collection number

unique identification of a test organism allocated by a recognized culture collection

3.70

culture condition

combination of growth media and manner of incubation used to promote germination, growth, and/or multiplication of microorganisms

Note 1 to entry: The manner of incubation can include the temperature, time, and any other conditions specified for incubation.

3.71

cycle complete

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

3.72

cycle parameter

value of a cycle variable including its tolerance used for control, monitoring, indication, and recording of an operating cycle

3.73

cycle time

<irradiation> period of time an irradiation container spends in each dwell position in a gamma process, used as a control parameter for dose

3.74

cycle variable

property used to control, monitor, indicate, or record an operating cycle

3.75

D value

D₁₀ value

time or dose required under stated conditions to achieve inactivation of 90 % of a population of the test microorganisms

3.76

dead leg

area of entrapment in vessel or piping that is not easily accessed

3.77

depyrogenation

process used to remove or deactivate pyrogenic substances to a specified level

Note 1 to entry: Pyrogenic substances include bacterial endotoxins.

3.78

desorption

removal of the sterilizing agent from the chamber and the load at the end of the exposure phase

3.79

development

act of elaborating a specification

3.80

dew point

temperature at which the saturation water vapour pressure is equal to the partial pressure of the water vapour in the atmosphere

3.81

direct support zone

protective area directly surrounding a critical processing zone

3.82

disinfectant

chemical or combination of chemicals used for disinfection

3.83

disinfecting agent

physical or chemical agent used for disinfection

3.84

disinfection

process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

3.85

disinfection temperature

minimum temperature on which the evaluation of the disinfection efficacy is based

3.86

disinfection time

period for which the process variable(s) is/are maintained at or above that/those specified

Note 1 to entry: Examples of process variables include temperature of the load, disinfectant concentration in the chamber.

3.87

dose mapping

<radiation> measurement of dose distribution and variability in material irradiated under specified conditions

3.88

dose uniformity ratio

<radiation> ratio of the maximum to the minimum absorbed dose within the irradiation container

3.89

dosimeter

device having a reproducible, measurable response to radiation that can be used to measure the absorbed dose in a given system

3.90

dosimetry

measurement of absorbed dose by the use of dosimeters

3.91

dosimetry system

interrelated elements used for determining absorbed dose, including dosimeters, instruments, associated reference standards, and procedures for their use

3.92

double-ended

having separate doors for loading and unloading in separate areas

3.93

drying stage

part of an operating cycle that is dedicated to removing moisture from the load

3.94

endoscope connector

device to interface with the fluid entry port of a channel of an endoscope that, where applicable, includes the tubing connected to the channel irrigation system of the washer-disinfector

3.95

endoscope leak test

set of actions to identify a loss of integrity

3.96

endoscope port

part of an endoscope to which the irrigation system of the washer-disinfector is connected to irrigate all or part of a channel

3.97

endoscope product family

group of endoscopes with comparable design, including the number, construction, and purpose of the different endoscope channels

3.98

endoscope surrogate device

item designed to represent construction elements of endoscope specific characteristics affecting the flow conditions in endoscope channels

Note 1 to entry: Elements can include channel length and diameter, connectors, channel separators, port closures, return valves, etc.

3.99

endoscope type test group

endoscopes for which the general channel design and specific characteristics affecting the flow conditions in the endoscope are similar

Note 1 to entry: The general channel design includes lengths and diameters. Characteristics affecting the flow conditions in the endoscope are, for example, connectors, channel separators, port closures, return valves.

Note 2 to entry: Similar implies that small variations can be possible. Endoscopes that show small variations in channel specifications that do not lead to a significant variation in the flow and pressure characteristic through the channels could be in the same endoscope type test group.

3.100

endoscope washer-disinfector

washer-disinfector intended to clean and disinfect loads comprising flexible endoscopes

3.101

endotoxin

lipopolysaccharide component of the cell wall of Gram-negative bacteria that is heat stable and elicits a variety of inflammatory responses in animals and humans

3.102

environmental control

application of engineering and/or procedural systems to maintain conditions in a defined space within specified limits

3.103

environmental isolate

microorganism cultured from processing or manufacturing environments

3.104

EO-cartridge

hermetically sealed container that holds a predetermined weight of ethylene oxide (EO) for single use

Note 1 to entry: The EO-cartridge is designed to be used in low volume chambers and/or to be activated while in the flexible sterilization bag, releasing EO.

3.105

equilibration time

period between the attainment of defined sterilization process parameters at the reference measurement point and the attainment of the specified sterilization process parameters at all points within the load

3.106

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

3.107

establish

determine by theoretical evaluation and confirm by experimentation

3.108

excipient

chemical or biological component other than an active ingredient that is included in a formulation

3.109

expanded measurement uncertainty

product of a combined standard measurement uncertainty and a factor larger than the number one

Note 1 to entry: The factor depends upon the type of probability distribution of the output quantity in a measurement model and on the selected coverage probability.

Note 2 to entry: The term “factor” in this definition refers to a coverage factor.

[SOURCE: ISO/IEC Guide 99:2007, 2.35, modified — The admitted term has been modified, and Note 3 to entry has been deleted.]

3.110

expiry date

date by which product should be used

A1 3.111

exposure stage

cycle stage between the introduction of the sterilizing agent or disinfecting agent into the chamber and when its microbicidal effect has become negligible

Note 1 to entry: The exposure stage comprises that part of the process for which microbial lethality is claimed. **A1**

3.112

extrinsic contamination

ingress of viable or non-viable extraneous material during the manufacturing process

3.113

F value

measure of microbiological lethality delivered by a heat process expressed in terms of the equivalent time, in minutes, at a specified temperature with reference to microorganisms with a specified z value

3.113.1

F_0 value

measure of microbiological lethality delivered by a moist heat sterilization process expressed in terms of the equivalent time, in minutes, at a temperature of 121,1 °C with reference to microorganisms with a z value of 10 K

A1 3.113.2

F_{BI0} value

expression of the resistance of a biological indicator calculated as the product of the logarithm to base 10 of the initial population of microorganisms and the D value **A1**

3.113.3

F_H value

measure of microbiological lethality delivered by a dry heat sterilization process expressed in terms of the equivalent time, in minutes, at a temperature of 160 °C with reference to microorganisms with a z value of 20 K

A1 3.113.4

$F_{BIOLOGICAL}$ value

expression of the delivered lethality of a process, measured in terms of actual kill of microorganisms on or in a biological indicator (BI) challenge system

Note 1 to entry: $F_{BIOLOGICAL}$ can be calculated by multiplying the D_{121} value by the difference between the log to the base ten of the starting population and the log to the base ten of the enumerated population after processing. **A1**

3.114

facultative organism

microorganism capable of both aerobic and anaerobic metabolism

3.115

fail safe

attribute of equipment, or its associated services, that ensures that a malfunction will not give rise to a hazardous situation

3.116

fault

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

3.117

filter

construct of porous material through which a fluid is passed to remove viable and/or non-viable particles

3.118

filter integrity test

non-destructive physical technical operation that can be correlated to the bacterial retention capability of a filter assembly

3.119

flexible sterilization bag

<EO-sterilization> container constructed from a malleable membrane that acts as the sterilization chamber

Note 1 to entry: The material from which the flexible sterilization bag is manufactured can be either permeable or impermeable to EO gas.

3.120

fluid

substance that continually deforms (flows) under applied shear force

EXAMPLE Liquid, gas, vapour, plasma.

3.121

flushing

purging
removing by displacement with a fluid

3.122

fraction positive

quotient in which the number of positive tests of sterility is given by the numerator, and the number of tests performed is given by the denominator

3.123

fractional cycle

operating cycle in which the exposure phase is reduced compared with that specified for the sterilization cycle

3.124

free draining

allowing the unimpeded flow of liquids towards the discharge point under the influence of gravity

3.125

gas concentration

weight of a specific gas in a given volume

Note 1 to entry: Concentration can be expressed as mg/l or g/m³.