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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.]

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**
D_{10} 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

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

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

3.113.2
F_{BIO} value
expression of the resistance of a biological indicator calculated as the product of the logarithm of the initial population of microorganisms and the *D* value

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

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/m^3.

3.126
gauge pressure
pressure for which the zero value is associated with atmospheric pressure

3.127
gowning procedure
specified actions for putting on protective garments in a manner commensurate with the cleanliness level of the room

3.128
growth promotion test
technical operation performed to demonstrate that a growth medium will support microbial multiplication

3.129
half cycle
test cycle in which the extent of treatment is reduced by 50 % as compared with an operating cycle

3.130
hazard
potential source of harm

[SOURCE: ISO/IEC Guide 51:2014, 3.2]

3.131
hazardous situation
circumstance in which people, property, or the environment is/are exposed to one or more hazards

[SOURCE: ISO/IEC Guide 51:2014, 3.4]

3.132
health care product
medical device, including *in vitro* diagnostic medical device, or medicinal product, including biopharmaceutical

3.133
holding time
period during which process parameters are maintained, within their specified tolerances

3.134
human waste
body fluids and excretions

EXAMPLE Faeces, urine, blood, pus, vomit, mucus.

3.135
human waste container
vessel for holding and transporting human waste

3.136
humidity
measure of water vapour present in a gas

Note 1 to entry: Humidity is usually expressed as absolute humidity (i.e. vapour pressure density), relative humidity, or dew point.

3.136.1
absolute humidity
measure of water vapour in the air, regardless of temperature

Note 1 to entry: It is expressed as grams of moisture per cubic meter of air (g/m^3).

3.136.2
relative humidity
measure of water vapour in the air expressed as a percentage of the maximum for a given temperature

Note 1 to entry: It is expressed as a percent.

3.137
inactivation curve
graphical representation of decrease in viability of a population of microorganisms with increasing exposure to a microbicidal agent under stated conditions

3.138
incremental dose
dose within a series of doses applied to a number of product, or portions thereof, and used in a dose setting method to obtain or confirm the sterilization dose

3.139
indicate
display a value, condition, or stage of process

3.140
indicator exposure period
duration between the initial attainment to the termination of the specified exposure conditions

3.141
indirect dose measurement
measurement of absorbed dose at a location remote from a directly measured dosimeter calculated by the application of factors

3.142
indirect support zone
location within the aseptic processing area that protects the direct support zone

Note 1 to entry: The required grade of cleanliness of the indirect support zone depends on the aseptic processing technologies and activities performed.

3.143
influence quantity
quantity that, in a direct measurement, does not affect the quantity that is actually measured, but affects the relation between the indication and the measurement result

[SOURCE: ISO/IEC Guide 99:2007, 2.52, modified — The examples and the notes to entry have been deleted.]

3.144
inoculated carrier
supporting material on or in which a specified number of viable test microorganisms has been deposited

3.145
intrinsic contamination
viable and non-viable foreign matter present in cell-based starting material

3.146
irradiation container
holder in which product is transported through the irradiator

Note 1 to entry: The holder can be a carrier, cart, tray, product carton, pallet, or other container.

3.147
irradiator operator
company or body responsible for irradiation of product

3.148
irrigation plan
<endoscope washer-disinfector> stipulated direction of flow of process fluids through the specified channels of an endoscope

3.149
isolator
<aseptic processing> enclosure capable of preventing ingress of contaminants by means of physical separation of the interior from the exterior that is capable of being subject to reproducible interior bio-decontamination, and where processors always remain separated from the interior of the enclosure by means of an absolute physical barrier

3.150
isolator system
isolator with transfer system(s) and ancillary equipment

3.151
labelling
label, instructions for use and any other information that is related to identification, technical description, intended purpose, and proper use of the health care product, but excluding shipping documents

[SOURCE: ISO 13485:2016, 3.8, modified — The term "medical device" has been replaced by "health care product".]

3.152
leachable
<filter> substance that can be released from a filter or filter assembly during normal use conditions

3.153
lethal rate
L
measure of inactivation per unit time at temperature, T, expressed in terms of a reference temperature, T_{ref}

Note 1 to entry: L is expressed as minutes at the reference temperature, T_{ref}, per minute at T.

Note 2 to entry: Lethal rate at any temperature can be calculated using the formula:

$$L = 10^{\frac{(T - T_{ref})}{z}}$$

where

T is the delivered temperature;

T_{ref} is the reference temperature;

z is the change in temperature that produces a tenfold change in D value.

3.154
liquid transport system
<washer-disinfector> components of equipment used to store, pump, or transport water and/or solutions, excluding pipework before the air break

3.155
load
product, equipment, or materials to be processed together within an operating cycle

3.156
load configuration
distribution and orientation of a load

3.157
loading door
means of access through which a load is passed into the chamber before processing

3.158
lumen device
item that consists of tube(s) or pipe(s)

3.159
manual cleaning
removal of contaminants from an item to the extent necessary for further processing or for intended use without the use of an automated process

3.160
master product
health care product or procedure set used to represent the most difficult to sterilize item in a product family or processing category

3.161
maximum acceptable dose
dose given in the process specification as the highest dose that can be applied to a specified product without compromising safety, quality, or performance

3.162
measurement accuracy
closeness of agreement between a measured quantity value and a true quantity value of a measurand

[SOURCE: ISO/IEC Guide 99:2007, 2.13, modified — The admitted terms and the notes to entry have been deleted.]

3.163
measurement precision
precision
closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions

Note 1 to entry: Measurement precision is usually expressed numerically by measures of imprecision, such as standard deviation, variance, or coefficient of variation under the specified conditions of measurement.

Note 2 to entry: The "specified conditions" can be, for example, repeatability conditions of measurement, intermediate precision conditions of measurement, or reproducibility conditions of measurement.

Note 3 to entry: Measurement precision is used to define "measurement repeatability", "intermediate measurement precision", and "measurement reproducibility".

Note 4 to entry: Sometimes "measurement precision" is erroneously used to mean measurement accuracy.

[SOURCE: ISO/IEC Guide 99:2007, 2.15]

3.164
measurement uncertainty
non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

[SOURCE: ISO/IEC Guide 99:2007, 2.26, modified — The notes to entry have been deleted.]

3.165
measuring chain
series of elements of a measuring instrument or measuring system, which constitutes the path of the measurement signal from the input (quantity subject to measurement) to the output (the result of the measurement)

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, 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 — The first two list items in Note 1 to entry have been added.]

3.167
medical device manufacturer
natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)

Note 1 to entry: This "natural or legal person" has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical devices in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

Note 2 to entry: The manufacturer's responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 3 to entry: "Design and/or manufacture", as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.

Note 4 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.

Note 5 to entry: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer, and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.

Note 6 to entry: An authorized representative, distributor, or importer who only adds its own address and contact details to the medical device or the packaging, without covering or changing the existing labelling, is not considered a manufacturer.

Note 7 to entry: To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.

[SOURCE: GHTF/SG1/N055:2009, 5.1, modified — "medical device" has been added to the term, and the footnotes have been deleted.]

3.168
method suitability
<microbiological> assessment of the test method to demonstrate its ability to allow microbial growth

3.169
microbial barrier
property of a sterile barrier system to minimize the risk of ingress of microorganisms

3.170
microbial characterization
process by which microorganisms are grouped into categories

Note 1 to entry: Categories can be broadly based, for example, on the use of selective media, colony or cellular morphology, staining properties, or other characteristics.

3.171
microbial contamination
presence of unintended bacteria, fungi, protozoa, or viruses

3.172
microbial inactivation
loss of ability of microorganisms to grow and/or multiply

3.173
microbial inactivation factor
measured change in microbial population caused by the lethal effect of the disinfection or sterilization process

Note 1 to entry: It is expressed as $\log_{10}$.

3.174
microbial reduction factor
extent to which the bioburden is reduced in tenfold increments

Note 1 to entry: It is expressed as $\log_{10}$.

3.175
microbial resistance
ability of a microorganism or population of microorganisms to withstand a microbial reduction process

3.176
microorganism
entity of microscopic size, encompassing bacteria, fungi, protozoa, and viruses

3.177
minimum effective concentration
MEC
lowest concentration of a chemical or product, used in a specified process, that achieves a claimed activity

3.178
minimum recommended concentration
MRC
lowest concentration of a chemical or product specified for use in a process

3.179
moist heat
thermal energy in the presence of moisture released by gaseous or liquid water

3.180
monitoring
continual checking, supervising, critically observing, or determining the status, in order to identify change from the performance level required or expected

[SOURCE: ISO Guide 73:2009, 3.8.2.1, modified — The note has been deleted.]

3.181
negative air pressure area
area where the ventilation system provides pressure below that of the adjacent area(s)

3.182
nominal population
stated number of viable microorganisms on or in a test piece

3.183
non-condensable gas
air and/or other gas which will not liquefy under the conditions of a saturated steam process

3.184
non-invasive device
device that does not penetrate inside the body, either through a body orifice or through the surface of the body

3.185
normal operation
use of equipment in accordance with the manufacturer's instructions and with all process parameters within the specified tolerances

3.186
obligate anaerobe
organism that only lives and grows in the absence of molecular oxygen

3.187
obstruction
<endoscope channel> partial or complete blockage

3.188
operating cycle
complete set of stages of a process that is carried out, in a specified sequence

Note 1 to entry: Loading and unloading are not part of the operating cycle.

[SOURCE: IEC 61010-2-040:2015, 3.2.105]

3.189
operating pressure
fluid pressure occurring during an operating cycle

3.190
overkill approach
method of defining a sterilization process that achieves a maximal sterility assurance level (SAL) for product substantially less than 10^{-6}

3.191
override
system by which an operating cycle can be interrupted or modified as necessary

3.192
packaging system
combination of a sterile barrier system and protective packaging

3.193
parametric release
declaration that product is sterile based on records demonstrating that the sterilization process variables were delivered within specified tolerances

3.194
penetration
<chemical indicator> migration through a substrate to its opposite surface

3.195
plateau period
equilibration time plus the holding time

3.196
pore size rating
nominal pore size of a filter as claimed and stated in the labelling

3.197
porous
<sterilizer load> permeable to water, air, or other fluids

3.198
port closure
<endoscope> device to close an endoscope port during processing in order to maintain the flow of process fluids throughout the length of the endoscope

EXAMPLE To close the suction valve port..

3.199
powered device
<washer-disinfector> surgical instrument which gives a rotating and/or oscillating movement to other surgical instruments

Note 1 to entry: The power applied to the driven instrument can be mechanical (from a motor, either through direct coupling, flexible axle, or belt) or by the flow of a pressurized fluid or compressed air.

EXAMPLE Dental hand pieces, orthopaedic saws, drills.

3.200
preconditioning
treatment of product, prior to the operating cycle, to attain specified values for temperature, relative humidity, and/or other process variables

3.201
preformed sterile barrier system
sterile barrier system that is supplied partially assembled for filling and final closure or sealing

3.202
pressure vessel
housing and its direct attachments up to the coupling point connecting it to other equipment, designed and built to contain fluids under pressure

Note 1 to entry: A vessel can be composed of more than one chamber.

[SOURCE: EN 13445-1:2014, 3.2; modified – In Note 1 to entry "may" has been replaced by "can".]

3.203
preventive action
action to eliminate the cause of a potential nonconformity or other potential undesirable situation

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

Note 2 to entry: Preventive action is taken to prevent occurrence whereas corrective action is taken to prevent recurrence.

[SOURCE: ISO 9000:2015, 3.12.1]

3.204
primary package
<biological indicator> element of the packaging system which maintains the integrity of the product

Note 1 to entry: The packaging system protects the inoculated carrier from damage and contamination without preventing penetration of the sterilizing agent.

3.205
process challenge device
PCD
item providing a defined resistance to a cleaning, disinfection, or sterilization process and used to assess performance of the process

3.206
process challenge location
PCL
site chosen within a load as the position at which the least microbiological inactivation is expected to be delivered

3.207
process chemical
formulation of substances intended for use in equipment

3.208
process confirmation study
exercise to verify control of intrinsic microbial contamination of manufacturing processes for cell-based health care products

3.209
process control
specific activities to ensure process requirements are achieved

3.210
process development
programme of activities performed to define the process based on product/packaging/loading pattern and equipment capabilities

3.211
process parameter
specified value for a process variable

Note 1 to entry: The specification for a process includes the process parameters and their tolerances.

3.212
process simulation
exercise that mimics the manufacturing process or portions of the process in order to demonstrate the capability of that process

3.213
process variable
chemical or physical attribute within a cleaning, disinfection, packaging, or sterilization process, changes in which can alter its effectiveness

EXAMPLE Time, temperature, pressure, concentration, humidity, wavelength.

3.214
processing
<preparation of medical devices> activity to prepare a new or used health care product for its intended use

3.215
processing category
collection of different product or product families that can be processed together

3.216
processor
<preparation of medical devices> organization and/or individual with the responsibility of carrying out actions necessary to prepare a new or reusable health care product for its intended use

3.217
product
tangible result of a process

EXAMPLE Raw material(s), intermediate(s), sub-assembly(ies), health care product(s).

3.218
product family
group or subgroup of product characterized by similar attributes determined to be equivalent for evaluation and processing purposes

3.219
protective packaging
configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use

3.220
qualification
activities undertaken to demonstrate that utilities, equipment, and methods or modes are suitable for their intended use and perform properly

Note 1 to entry: Qualification of equipment and/or processes generally includes installation qualification, operational qualification, and performance qualification.

[SOURCE: US Pharmacopeia PF40/1083-1:2014; modified]

3.220.1
design qualification
process for verification that the proposed specification for the facility, equipment, or system meets the expectation for the intended use

3.220.2
installation qualification
IQ
process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation comply with the approved specification

3.220.3
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

3.220.4
performance qualification
PQ
process of establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements

3.220.5
requalification
repetition of part or all of validation for the purpose of confirming the continued acceptability of a specified process

3.221
reagent
<cell-based health care product> material used for cellular growth, differentiation, selection, purification, or other critical manufacturing steps, but that is not intended to be part of the final product

3.222
recognized culture collection
depository authority under the Budapest Treaty on *The International Recognition of the Deposit of Microorganisms for the Purposes of Patent and Regulation*

3.223
record, verb
<data> collect, store, and make accessible

3.224
recorder
equipment that records and produces a permanent record of information graphically, digitally, or electronically

3.225
recovery efficiency
<bioburden> measure of the ability of a specified technique to remove, collect, and/or culture microorganisms from a product

3.226
reference load
specified load created to represent combinations of items that provide defined challenge(s) to a process

3.227
reference measurement point
location of the sensor controlling the operating cycle

3.228
reference microorganism
microbial strain obtained from a recognized culture collection

3.229
reference standard
measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location

[SOURCE: ISO/IEC Guide 99:2007, 5.6, modified — The term name has been simplified.]

3.230
repeatability
condition of measurement, out of a set of conditions that includes the same measurement procedure, same operators, same measuring system, same operating conditions, and same location, and replicate measurements on the same or similar objects over a short period of time

[SOURCE: ISO/IEC Guide 99:2007, 2.20, modified — The term name has been simplified and the notes omitted.]

3.231
reproducibility
condition of measurement, out of a set of conditions that includes different locations, processors, measuring systems, and replicate measurements on the same or similar objects

Note 1 to entry: The different measuring systems may use different measurement procedures.

Note 2 to entry: A specification should give the conditions changed and unchanged to the extent practical.

[SOURCE: ISO/IEC Guide 99:2007, 2.24, modified — The term name has been simplified.]

3.232
residues challenge device
item used to assess the effectiveness of desorption

3.233
resistometer
test equipment designed to create specified combinations of the physical and/or chemical parameters of a sterilization process

3.234
response time
τ_{90}
<sensor> period required for a 90 % change in sensor output when exposed to a step change in the variable being measured

3.235
reusable container
rigid sterile barrier system designed to be used repeatedly

3.236
reusable medical device
medical device designated or intended by the manufacturer as suitable for processing and reuse

Note 1 to entry: This is not a medical device that is designated or intended by the manufacturer for single use only.

3.237
rinsing
removing process residues through displacement by, and dilution with, water

3.238
routine test
technical operation conducted periodically to establish that the operational performance of the equipment or process remains within the limits established during validation

3.239
safety data sheet
SDS
document specifying the properties of a substance, its potential hazardous effects for humans and the environment, and the precautions necessary to handle and dispose of the substance safely

3.240
sample item portion
specified part of a health care product that is tested

3.241
saturated steam
water vapour in a state of equilibrium between its liquid and gas phases

3.242
scan length
dimension of the irradiation zone, perpendicular to the scan width and direction of the electron beam at a specified distance from the accelerator window

Note 1 to entry: ISO 12749-4:2015 uses "beam length" to mean the same thing that "scan length" means in this document.

3.243
scan width
dimension of the irradiation zone in the direction that the beam is scanned, perpendicular to the scan length and direction of the electron beam at a specified distance from the accelerator window

Note 1 to entry: ISO 12749-4:2015 uses "beam width" to mean the same thing that "scan width" means in this document.

3.244
seal
<packaging> result of joining surfaces together by fusion to form a microbial barrier

3.245
seal integrity
<packaging> characteristics of a seal to minimize the risk of ingress of microorganisms

3.246
seal strength
mechanical capacity of a seal to withstand force

3.247
secondary package
<biological indicators> container in which biological indicators are packed for transport and storage

3.248
self-contained biological indicator
biological indicator presented such that the primary package, intended for incubation, contains the incubation medium required for incubation and recovery of the test organism

3.249
self-disinfection cycle
operating cycle intended to disinfect all liquid transport systems' piping, chamber(s), tanks, and other components which come into contact with the water and/or solutions used for cleaning, disinfecting, and rinsing the load

Note 1 to entry: The self-disinfection cycle is used without a load in a washer-disinfector.

3.250
separative device
equipment utilizing constructional and dynamic means to create assured levels of separation between the inside and outside of a defined volume

Note 1 to entry: Some industry-specific examples of separative devices are clean air hoods, containment enclosures, glove boxes, isolators, and mini-environments.

3.251
service life
useful life
number of processing cycles and/or lifetime up to which a product is claimed to remain suitable and safe for its intended use when used according to the labelling

3.252
services
supplies from an external source needed for the function of equipment

3.253
shift
scheduled period of work or production staffed by a single defined group of workers

3.254
simulated product
<radiation sterilization> material with attenuation and scattering properties similar to those of product, material, or substance to be irradiated

Note 1 to entry: Simulated product is used as a substitute for the actual product, material, or substance to be irradiated. When used in routine production runs to compensate for the absence of product, simulated product is sometimes referred to as compensating dummy. When used for dose mapping, simulated product is sometimes referred to as phantom material.

3.255
single-use medical device
medical device labelled or intended to be used on one individual during a single procedure

3.256
small steam sterilizer
steam sterilizer which has a chamber volume of less than 60 litres and is unable to accept a sterilization module

3.257
soil
natural or artificial contamination on a device or surface following its use or simulated use

3.258
spatial resolution
ability to detect change in dose in two dimensions

3.259
specify
stipulate in detail within an approved document

3.260
spore log reduction
SLR
negative exponent to the base 10 describing the decrease in the number of spores

Note 1 to entry: It is expressed as a logarithm.

3.261
stabilization period
elapsed time from the attainment of the minimum specified exposure conditions until the end of the specified time to achieve steady state conditions

3.262
stage
<operating cycle> part of an operating cycle with a specified function

EXAMPLE Air removal stage, plateau period, drying stage, final air admission stage.

3.263
standard distribution of resistances
SDR
reference set of resistances of microorganisms and corresponding probabilities of occurrence

3.264
standard measurement uncertainty
measurement uncertainty expressed as a standard deviation

[SOURCE: ISO/IEC Guide 99:2007, 2.30]

3.265
stated value
SV
<chemical indicator> value or values of a critical variable at which an indicator is designed to reach its endpoint

3.266
steady state period
<indicator> portion of the exposure period which begins after the stabilization period and terminates at the end of the exposure period

3.267
steam penetration resistance
challenge to a moist heat sterilization process from a medical device, including any sterile barrier system, that can delay attainment of the process parameters

3.268
sterilant
chemical or combination of chemicals used to generate a sterilizing agent

3.269
sterilant/sterilizing agent injection
introduction of sterilant/sterilizing agent into the evacuated chamber until the set operating pressure has been attained or the specified quantity of sterilant/sterilizing agent has been delivered

3.270
sterilant/sterilizing agent injection time
duration of the stage beginning with the first introduction of the sterilant/sterilizing agent into the chamber and ending when addition of sterilant/sterilizing agent ceases

3.271
sterile
free from viable microorganisms

3.272
sterile barrier system
SBS
minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use

3.273
sterile fluid-path packaging
system of protective port covers and/or packaging designed to ensure sterility of the portion of the medical device intended for contact with fluids

EXAMPLE The interior of the tubing for administration of an intravenous fluid.

3.274
sterility
state of being free from viable microorganisms

Note 1 to entry: In practice, no such absolute statement regarding the absence of microorganisms can be proven.

3.275
sterility assurance level
SAL
probability of a single viable microorganism occurring on an item after sterilization

Note 1 to entry: It is expressed as the negative exponent to the base 10.

3.276
sterilizing filtration
removal of viable microorganisms from fluids by passage of the fluid through a filter under specified process conditions resulting in a sterile filtrate

3.277
sterilization
validated process used to render product free from viable microorganisms

Note 1 to entry: In a sterilization process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

3.278
sterilization compatibility
<packaging> attributes of the packaging material and/or system that allow it both to withstand the sterilization process and attain the required conditions for sterilization within the packaging system

3.279
sterilization cycle
predetermined sequence of stages performed in a sterilizer to achieve product free of viable microorganisms

3.280
sterilization dose
SD
<radiation> minimum dose to achieve the specified requirements for sterility

3.281
sterilization dose audit
<radiation> exercise undertaken to confirm the appropriateness of an established sterilization dose

3.282
sterilization in place
method of sterilization of the internal surfaces of parts of the equipment or an entire process system *in situ*, without disassembly, using appropriate sterilizing agents

3.283
sterilization module
rectangular parallelepiped of dimensions 300 mm (height) × 600 mm (length) × 300 mm (width)

3.284
sterilization process
series of actions or operations needed to achieve the specified requirements for sterility

Note 1 to entry: This series of actions includes pre-treatment of product (if necessary), exposure under specified conditions to the sterilizing agent, and any necessary post treatment. The sterilization process does not include any cleaning, disinfection, or packaging operations that precede sterilization.

3.285
sterilization system
sterilizer and ancillary equipment associated with delivering the sterilization process

Note 1 to entry: In dry heat processing, a sterilization system might be used for depyrogenation.

3.286
sterilization temperature
minimum temperature on which the evaluation of the sterilization efficacy is based

3.287
sterilizer
equipment designed to achieve sterilization

3.288
sterilizing agent
physical or chemical entity, or combination of entities, having sufficient microbicidal activity to achieve sterility under specified conditions

3.289
storage cabinet
<endoscope> equipment that maintains the microbiological quality of processed thermolabile endoscopes

3.290
storage solution
liquid in which a medical device in its final form is presented for use

3.291
surrogate product
item designed to represent product in process simulations and which is comparable with the actual product

3.292
survival-kill window
extent of exposure to a sterilization process under specified conditions where there is a transition from all biological indicators showing growth to all biological indicators showing no growth

3.293
temperature band
range of temperatures expressed as the minimum and the maximum temperatures which prevail during the specified period of a cycle

Note 1 to entry: A modifier to the term may be applied to the term and a note added to cover specific variations in the use of this term in specific standards, e.g. washing temperature band, sterilization temperature band.

3.293.1
temperature band
<moist heat sterilization> temperature range, the minimum of which is the sterilization temperature

3.294
terminal process
final step of processing to render a medical device safe and ready for its intended use

3.295
terminal sterilization
process whereby a product is sterilized within its sterile barrier system

3.296
terminally sterilized
condition of a product that has been exposed to a sterilization process in its sterilized barrier system

3.297
test equilibration time
<indicator> time elapsed after the chamber reference temperature attains the set operating temperature until the temperature within the standard test pack is the same as the chamber reference temperature

3.298
test for sterility
technical operation specified in a pharmacopoeia performed on product following an aseptic process or exposure to a sterilization process

3.299
test of sterility
technical operation performed as part of development, validation, or requalification to determine the presence or absence of viable microorganisms on product or portions thereof

3.300
test soil
formulation designed for use as a substitute for a contaminant or debris found on a device after use

3.301
thermal disinfection
disinfection achieved by the action of moist heat

3.302
thermolabile
readily damaged by heat

3.303
tissue
organization of cells, cells and extra-cellular constituents, or extra-cellular constituents

3.304
transfer port
interface between the interior of an isolator and ancillary isolator equipment

3.305
transit dose
dose absorbed during travel of product or source to or from the non-irradiation to the irradiation position

3.306
type test
technical operation to verify conformity of an equipment type to a standard or specification, and to establish data for reference in subsequent tests

3.307
uncertainty budget
statement of a measurement uncertainty, of the components of that measurement uncertainty, and of their calculation and combination

Note 1 to entry: An uncertainty budget should include the measurement model, estimates, and measurement uncertainties associated with the quantities in the measurement model, covariances, type of applied probability density functions, degrees of freedom, type of evaluation of measurement uncertainty, and any coverage factor.

[SOURCE: ISO/IEC Guide 99:2007, 2.33]

3.308
unidirectional airflow
air stream which has a specified direction

3.309
unit operation
defined part of a manufacturing process

3.310
unloading door
means through which a load is removed from the chamber after processing

3.311
usable chamber space
specified geometry within the chamber that is available to accept the load

3.312
user-assembled pack
<chemical indicator> combination of the indicator and the test load created at the point of use

3.313
validation
confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word "validated" is used to designate the corresponding status.

Note 3 to entry: The use conditions for validation can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13, modified — "process" has been added to the definition.]

3.314
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word "verified" is used to designate the corresponding status.

[SOURCE: ISO 9000:2015, 3.8.12, modified — The original Note 2 to entry has been deleted and Note 3 has been renumbered as Note 2 accordingly.]

3.315
verification dose
dose of radiation predicted to give a predetermined sterility assurance level (SAL) greater than or equal to 10^{-2} used in establishing the sterilization dose

3.316
viable count
value established from enumeration of recoverable colony-forming units

3.317
visible change
<chemical indicator> change specified by the indicator manufacturer, that is observed in Type 1 indicators after exposure to one or more process variables

3.318
volume
quantity of three-dimensional space enclosed by a closed surface

3.318.1
chamber volume
enclosed space of a chamber, including the volume of nozzles to the first connection or weld, and excluding the volume of permanent internal parts

3.318.2
dead volume
<washer-disinfector> enclosed space of pipework which is not purged by the usual flow of liquids during the operating cycle

3.318.3
load volume
space occupied by product and any packaging and carrier(s)

3.319
washer-disinfector
WD
equipment designed to clean and disinfect product

3.320
washer-disinfector accessory
items or attachments, including connectors, required to process a medical device in a washer-disinfector

3.321
washing
removal of contaminants from surfaces by means of an aqueous fluid

3.322
washing temperature
minimum temperature of the washing temperature band

3.323
washing time
period for which the cycle variables are maintained within the values specified for washing

3.324
water charge
volume of water from which the steam for a sterilization cycle is generated

3.325
works test
series of technical operations performed prior to delivery to demonstrate compliance of a piece of equipment with its specification

3.326
***z* value**
change in temperature of a thermal sterilization or disinfection process that produces a tenfold change in *D* value

Note 1 to entry: It is expressed in degree Celsius (°C).

3.327
$\sigma_{process}$
standard uncertainty for setting process target doses

Annex A
(informative)

Summary of standards in which each term is included in their respective Clause 3

References [5] to [10], [12] to [20], [22] to [24], [26] to [29], [31] , [33] to [34], [36] to [54], and [56] to [66] are the standards referenced in Annex A. The standards are referenced with the stages at the time of publication of this document.

Ref	Term	Relevant standards
3.1	A_0	ISO 15883-1:2006 + Amd1:2014; ISO 15883-2:2006; ISO 15883-3:2006; ISO/FDIS 15883-4:2018; ISO 15883-6:2011
3.2	absolute pressure	EN 285:2015+ prA1:2018; EN 764-1:2004
3.3	absorbed dose	ISO 11137-1:2006 + Amd1:2013; ISO/TS 13004:2013
3.4	access device	EN 285:2015+ prA1:2018; EN 14180:2014
3.5	action level	ISO 13408-1:2008 + Amd1:2013; ISO/CD 15883-5:2017
3.6	active ingredient	ISO 18362:2016
3.7	aeration	EN 1422:2014; EN 14180:2014; prEN17180:2017; ISO 11135:2014 + FDAmd 1; ISO/FDIS 25424:2018
3.8	air break	ISO/FDIS 15883-4:2018
3.9	air detector	ISO 17665-1:2006
3.10	airlock	ISO 13408-1:2008 + Amd1:2013
3.11	alert level	ISO 13408-1:2008 + Amd1:2013; ISO/CD 15883-5:2017
3.12	analyte	ISO/FDIS 15883-4:2018; ISO/CD 15883-5:2017
3.13	aseptic presentation	ISO/FDIS 11607-1:2018; ISO/FDIS 11607-2:2018
3.14	aseptic processing	EN 556-2:2015; ISO 13408-1:2008 + Amd1:2013
3.15	aseptic processing area	ISO 13408-1:2008 + Amd1:2013
3.16	aseptic technique	ISO/DIS 11138-7:2017;
3.17	assurance of sterility	ISO/TS 19930:2017
3.18	automatic controller	EN 285:2015+ prA1:2018; EN 1422:2014; EN 13060:2014+ prA1:2017; EN 14180:2014; prEN17180:2017; ISO 15883-1:2006 + Amd1:2014; ISO 17665-1:2006
3.19	bacterial challenge test	ISO 13408-2:2018
3.20	bacteriostasis/fungistasis test	ISO/DIS 11737-2:2018
3.21	batch	ISO 11137-2:2013; ISO 11737-1:2018; ISO/TS 13004:2013; ISO/DIS 14160:2018; ISO 20857:2010
3.22	bedpan washer-disinfector	ISO 15883-1:2006 + Amd1:2014
3.23	bioburden	EN 556-1:2001; EN 556-2:2015; ISO 11135:2014 + FDAmd 1; ISO 11137-1:2006 + Amd1:2013; ISO 11137-2:2013; ISO/DIS 11138-7:2017; ISO/FDIS 11607-1:2018; ISO/FDIS 11607-2:2018; ISO 11737-1:2018; ISO/DIS 11737-2:2018; ISO/TS 13004:2013; ISO 13408-1:2008 + Amd1:2013; ISO 13408-2:2018; ISO/DIS 14160:2018; ISO 14937:2009; ISO 15883-1:2006 + Amd1:2014; ISO 17665-1:2006; ISO/TS 19930:2017; ISO 20857:2010;ISO/FDIS 25424:2018

Ref	Term	Relevant standards
3.24	**bioburden correction factor**	ISO 11737-1:2018
3.25	**bioburden estimate**	ISO 11737-1:2018
3.26	**bioburden spike**	ISO 11737-1:2018
3.27	**bio-decontamination**	ISO 13408-1:2008 + Amd1:2013
3.28	**biological contaminant**	ISO 18362:2016
3.29	**biological indicator**	EN 1422:2014; EN 13060:2014+ prA1:2017; EN 14180:2014; prEN17180:2017; ISO 11135:2014+ FDAmd 1; ISO 11137-1:2006 + Amd1:2013; ISO 11138-1:2017; ISO/DIS 11138-7:2017; ISO/CD 11138-8:2015; ISO 14937:2009; ISO 17665-1:2006; ISO 18472:2018; ISO/TS 19930:2017; ISO 20857:2010; ISO/FDIS 25424:2018
3.30	**block**	ISO/FDIS 15883-4:2018
3.31	**calibration**	EN 1422:2014; EN 13060:2014+ prA1:2017; ISO 11135:2014+ FDAmd 1; ISO 11137-1:2006 + Amd1:2013; ISO 15883-1:2006 + Amd1:2014; ISO 17665-1:2006; ISO 18472:2018; ISO 20857:2010; ISO/FDIS 25424:2018
3.32	**calorifier**	ISO 15883-1:2006 + Amd1:2014
3.33	**carrier**	ISO 11138-1:2017; ISO/CD 11138-8:2015; ISO/DIS 14160:2018
3.34	**cell-based**	ISO 18362:2016
3.35	**cell-processing area**	ISO 18362:2016
3.36	**chamber**	EN 285:2015+ prA1:2018; EN 13060:2014+ prA1:2017; EN 14180:2014; prEN17180:2017; ISO 15883-1:2006 + Amd1:2014; ISO 17665-1:2006
3.37	**chamber pre-heating**	EN 14180:2014; prEN17180:2017
3.38	**chamber reference temperature**	ISO 11140-4:2007
3.39	**change control**	ISO 11137-1:2006 + Amd1:2013; ISO 14937:2009; ISO/TS 19930:2017; ISO 20857:2010; ISO/FDIS 25424:2018
3.40	**channel separator**	ISO/FDIS 15883-4:2018
3.41	**chemical compatibility**	ISO 13408-2:2018
3.42	**chemical disinfection**	ISO 15883-1:2006 + Amd1:2014
3.43 3.43.1	**chemical indicator** **chemical indicator system**	EN 13060:2014+ prA1:2017; ISO 11135:2014 + FDAmd 1; ISO 11140-1:2014; ISO 11140-5:2007; ISO 14937:2009; ISO 15882:2008; ISO 17665-1:2006; ISO 18472:2018; ISO/TS 19930:2017; ISO 20857:2010; ISO/FDIS 25424:2018
3.44	**chemical indicator endpoint**	ISO 11140-1:2014; ISO 15882:2008
3.45	**clean**	ISO/CD 15883-5:2017
3.46	**cleaning**	ISO 13408-1:2008 + Amd1:2013; ISO 15883-1:2006 + Amd1:2014; ISO 17664:2017
3.47	**cleaning agent**	ISO 13408-4:2005
3.48	**clean-in-place**	ISO 13408-4:2005
3.49	**clinical use**	ISO/CD 15883-5:2017
3.50	**closure**	ISO/FDIS 11607-1:2018; ISO/FDIS 11607-2:2018
3.51	**closed system**	ISO 18362:2016
3.52	**closure integrity**	ISO/FDIS 11607-1:2018; ISO/FDIS 11607-2:2018
3.53	**colony forming unit**	ISO 11138-1:2017; ISO/FDIS 15883-4:2018
3.54	**combination product**	ISO 13408-1:2008 + Amd1:2013

Ref	Term	Relevant standards
3.55	**combined standard measurement uncertainty**	ISO 11137-3:2017
3.56	**come-down period**	ISO 18472:2018
3.57	**come-up period**	ISO 18472:2018
3.58	**conditioning**	EN 1422:2014; EN 14180:2014; prEN17180:2017; ISO 11135:2014 + FDAmd 1; ISO/FDIS 25424:2018
3.59	**containment**	ISO 18362:2016
3.60	**containment area**	ISO 18362:2016
3.61	**containment facility**	ISO 18362:2016
3.62	**continuous process machine**	ISO 15883-1:2006 + Amd1:2014
3.63	**control**	EN 1422:2014
3.64	**correction**	ISO 11137-1:2006 + Amd1:2013; ISO 11737-1:2018; ISO/TS 13004:2013; ISO 13408-1:2008 + Amd1:2013; ISO 14937:2009; ISO 17665-1:2006; ISO/TS 19930:2017; ISO 20857:2010
3.65	**corrective action**	ISO 11137-1:2006 + Amd1:2013; ISO 11737-1:2018; ISO/TS 13004:2013; ISO 13408-1:2008 + Amd1:2013; ISO 14937:2009; ISO 17665-1:2006; ISO/TS 19930:2017; ISO 20857:2010
3.66	**coverage factor**	ISO 11137-3:2017
3.67	**critical processing zone**	ISO 13408-1:2008 + Amd1:2013
3.68	**critical surface**	ISO 13408-1:2008 + Amd1:2013
3.69	**culture collection number**	ISO 11138-1:2017
3.70	**culture conditions**	ISO 11138-1:2017; ISO/CD 11138-8:2015; ISO 11737-1:2018; ISO/DIS 11737-2:2018
3.71	**cycle complete**	EN 285:2015+ prA1:2018; EN 1422:2014; EN 14180:2014; prEN17180:2017; ISO 15883-1:2006 + Amd1:2014
3.72	**cycle parameter**	EN 285:2015+ prA1:2018; EN 13060:2014+ prA1:2017; EN 14180:2014; prEN17180:2017
3.73	**cycle time**	ISO/TS WD 11137-4:2017
3.74	**cycle variable**	EN 14180:2014; prEN17180:2017
3.75	***D* value** **D_{10} value**	ISO 11135:2014 + FDAmd 1; ISO 11137-1:2006 + Amd1:2013; ISO 11137-2:2013; ISO 11138-1:2017; ISO/DIS 11138-7:2017; ISO/CD 11138-8:2015; ISO/DIS 14160:2018; ISO 15883-1:2006 + Amd1:2014; ISO 17665-1:2006; ISO 20857:2010; ISO/FDIS 25424:2018
3.76	**dead leg**	ISO 13408-4:2005; ISO 13408-5:2006
3.77	**depyrogenation**	ISO 13408-1:2008 + Amd1:2013; ISO 20857:2010
3.78	**desorption**	EN 14180:2014; prEN17180:2017; ISO/FDIS 25424:2018
3.79	**development**	ISO 11135:2014 + FDAmd 1; ISO 11137-1:2006 + Amd1:2013; ISO 14161:2009; ISO 14937:2009; ISO 17665-1:2006; ISO/TS 19930:2017
3.80	**dew point**	ISO 11135:2014 + FDAmd 1
3.81	**direct support zone**	ISO 13408-1:2008 + Amd1:2013
3.82	**disinfectant**	ISO 13408-1:2008 + Amd1:2013
3.83	**disinfecting agent**	ISO 17664:2017; ISO/FDIS 15883-4:2018
3.84	**disinfection**	ISO 13408-1:2008 + Amd1:2013; ISO 15883-1:2006 + Amd1:2014; ISO/FDIS 15883-4:2018; ISO 17664:2017
3.85	**disinfection temperature**	ISO 15883-1:2006 + Amd1:2014

Ref	Term	Relevant standards
3.86	**disinfection time**	ISO 15883-1:2006 + Amd1:2014
3.87	**dose mapping**	ISO 11137-1:2006 + Amd1:2013; ISO/TS 13004:2013
3.88	**dose uniformity ratio**	ISO 11137-3:2017
3.89	**dosimeter**	ISO 11137-3:2017
3.90	**dosimetry**	ISO 11137-3:2017
3.91	**dosimetry system**	ISO 11137-3:2017
3.92	**double-ended**	EN 285:2015+ prA1:2018; EN 13060:2014+ prA1:2017; EN 14180:2014; prEN17180:2017; ISO 15883-1:2006 + Amd1:2014
3.93	**drying stage**	EN 16442:2015
3.94	**endoscope connector**	ISO/FDIS 15883-4:2018
3.95	**endoscope leak test**	ISO/FDIS 15883-4:2018
3.96	**endoscope port**	ISO/FDIS 15883-4:2018
3.97	**endoscope product family**	ISO/FDIS 15883-4:2018
3.98	**endoscope surrogate device**	EN 16442:2015; ISO/FDIS 15883-4:2018
3.99	**endoscope type test group**	ISO/FDIS 15883-4:2018
3.100	**endoscope washer-disinfector**	ISO 15883-1:2006 + Amd1:2014
3.101	**endotoxin**	ISO 13408-1:2008 + Amd1:2013
3.102	**environmental control**	ISO 17665-1:2006; ISO/FDIS 25424:2018
3.103	**environmental isolate**	ISO 13408-1:2008 + Amd1:2013
3.104	**EO-cartridge**	ISO DTS 19572:2018
3.105	**equilibration time**	EN 285:2015+ prA1:2018; EN 13060:2014+ prA1:2017; EN 14180:2014; ISO 11140-5:2007; ISO 17665-1:2006; ISO/FDIS 25424:2018
3.106	**equipment maintenance**	EN 285:2015+ prA1:2018; ISO 17665-1:2006
3.107	**establish**	ISO 11135:2014 + FDAmd 1; ISO 11137-1:2006 + Amd1:2013; ISO 11737-1:2018; ISO 14937:2009; ISO 17665-1:2006; ISO/TS 19930:2017; ISO 20857:2010; ISO/FDIS 25424:2018
3.108	**excipient**	ISO 18362:2016
3.109	**expanded measurement uncertainty**	ISO 11137-3:2017
3.110	**expiry date**	ISO/FDIS 11607-1:2018; ISO/FDIS 11607-2:2018
3.111	**exposure phase**	EN 1422:2014; EN 14180:2014; ISO 11135:2014 + FDAmd 1; ISO 11140-4:2007; ISO/DIS 14160:2018; ISO 17665-1:2006; ISO 20857:2010; ISO/FDIS 25424:2018
3.112	**extrinsic contamination**	ISO 13408-7:2012; ISO 18362:2016]
3.113	***F* value**	ISO 20857:2010
3.113.1	**F_0 value**	ISO 17665-1:2006
3.113.2	**F_{BIO} value**	ISO/CD 11138-8:2015; ISO/FDIS 25424:2018
3.113.3	**F_H value**	ISO 20857:2010
3.114	**facultative organism**	ISO 11737-1:2018; ISO/DIS 11737-2:2018
3.115	**fail safe**	ISO 15883-1:2006 + Amd1:2014
3.116	**fault**	EN 285:2015+ prA1:2018; EN 1422:2014; EN 13060:2014+ prA1:2017; prEN17180:2017; ISO 11135:2014 + FDAmd 1; ISO 11137-1:2006 + Amd1:2013; ISO 14937:2009; ISO 15883-1:2006 + Amd1:2014; ISO 17665-1:2006; ISO 20857:2010; ISO/FDIS 25424:2018

Ref	Term	Relevant standards
3.117	**filter**	ISO 13408-2:2018
3.118	**filter integrity test**	ISO 13408-2:2018
3.119	**flexible sterilization bag**	ISO /DTS 19572:2018
3.120	**fluid**	ISO 13408-2:2018; ISO 15883-1:2006 + Amd1:2014
3.121	**flushing** purging	EN 1422:2014; ISO 11135:2014 + FDAmd 1; ISO 15883-1:2006 + Amd1:2014
3.122	**fraction positive**	ISO 11137-2:2013; ISO 20857:2010
3.123	**fractional cycle**	ISO 11135:2014 + FDAmd 1
3.124	**free draining**	ISO 15883-1:2006 + Amd1:2014
3.125	**gas concentration**	ISO/DTS 21387:2018
3.126	**gauge pressure**	EN 285:2015+ prA1:2018
3.127	**gowning procedure**	ISO 13408-1:2008 + Amd1:2013
3.128	**growth promotion test**	ISO/DIS 11737-2:2018
3.129	**half cycle**	ISO 11135:2014 + FDAmd 1
3.130	**hazard**	EN 13060:2014+ prA1:2017
3.131	**hazardous situation**	EN 13060:2014+ prA1:2017
3.132	**health care product**	ISO 11135:2014 + FDAmd 1; ISO 11137-1:2006 + Amd1:2013; ISO/TS 13004:2013; ISO 13408-1:2008 + Amd1:2013; ISO 14937:2009; ISO 17665-1:2006; ISO 18362:2016; ISO/TS 19930:2017; ISO 20857:2010
3.133	**holding time**	EN 285:2015+ prA1:2018; EN 13060:2014+ prA1:2017; EN 14180:2014; prEN17180:2017; ISO/DIS 11138-7:2017; ISO 15883-1:2006 + Amd1:2014; ISO 17665-1:2006; ISO/FDIS 25424:2018
3.134	**human waste**	ISO 15883-1:2006 + Amd1:2014; ISO 15883-3:2006
3.135	**human waste container**	ISO 15883-1:2006 + Amd1:2014; ISO 15883-3:2006
3.136	**humidity**	ISO/DTS 21387:2018
3.136.1	**absolute humidity**	ISO/DTS 21387:2018
3.136.2	**relative humidity**	ISO/DTS 21387:2018
3.137	**inactivation curve**	ISO 11135:2014 + FDAmd 1; ISO 11138-1:2017; ISO 14937:2009; ISO/TS 19930:2017; ISO 20857:2010; ISO/FDIS 25424:2018
3.138	**incremental dose**	ISO 11137-2:2013
3.139	**indicate**	EN 1422:2014
3.140	**indicator exposure period**	ISO 18472:2018
3.141	**indirect dose measurement**	ISO 11137-3:2017
3.142	**indirect support zone**	ISO 13408-1:2008 + Amd1:2013
3.143	**influence quantity**	ISO/TS WD 11137-4:2017
3.144	**inoculated carrier**	EN 14180:2014; ISO 11138-1:2017; ISO/DIS 11138-7:2017; ISO/CD 11138-8:2015; ISO/DIS 14160:2018; ISO/FDIS 15883-4:2018ISO 20857:2010; ISO/FDIS 25424:2018
3.145	**intrinsic contamination**	ISO 18362:2016
3.146	**irradiation container**	ISO 11137-1:2006 + Amd1:2013
3.147	**irradiator operator**	ISO 11137-1:2006 + Amd1:2013
3.148	**irrigation plan**	ISO/FDIS 15883-4:2018
3.149	**isolator**	ISO 13408-1:2008 + Amd1:2013; ISO 13408-6:2005 + Amd1:2013
3.150	**isolator system**	ISO 13408-6:2005 + Amd1:2013

Ref	Term	Relevant standards
3.151	**labelling**	ISO/FDIS 11607-1:2018; ISO/FDIS 11607-2:2018
3.152	**leachable**	ISO 13408-2:2018
3.153	**lethal rate**	ISO 20857:2010
3.154	**liquid transport system**	ISO/FDIS 15883-4:2018
3.155	**load**	EN 1422:2014; EN 13060:2014+ prA1:2017; EN 14180:2014; prEN17180:2017; ISO 11135:2014 + FDAmd 1; ISO 14937:2009; ISO 15883-1:2006 + Amd1:2014; ISO/CD 15883-5:2017; ISO 17665-1:2006; ISO/TS 19930:2017; ISO 20857:2010; ISO/FDIS 25424:2018
3.156	**load configuration**	ISO 17665-1:2006
3.157	**loading door**	EN 14180:2014; ISO 15883-1:2006 + Amd1:2014
3.158	**lumen device**	ISO 15883-2:2006
3.159	**manual cleaning**	ISO 17664:2017
3.160	**master product**	ISO/TS 17665-3:2013
3.161	**maximum acceptable dose**	ISO 11137-1:2006 + Amd1:2013
3.162	**measurement accuracy**	ISO 18472:2018
3.163	**measurement precision**	ISO 18472:2018
3.164	**measurement uncertainty**	ISO 11137-1:2006 + Amd1:2013; ISO 11137-3:2017
3.165	**measuring chain**	EN 285:2015+ prA1:2018; prEN17180:2017; ISO 17665-1:2006
3.166	**medical device**	EN 285:2015+ prA1:2018; EN 556-1:2001; EN 556-2:2015; EN 1422:2014; EN 13060:2014+ prA1:2017; EN 14180:2014; prEN17180:2017; ISO 11135:2014 + FDAmd 1; ISO 11137-1:2006 + Amd1:2013; ISO/FDIS 11607-1:2018; ISO/FDIS 11607-2:2018; ISO 11737-1:2018; ISO/DIS 11737-2:2018; ISO/TS 13004:2013; ISO/DIS 14160:2018; ISO 14937:2009; ISO 15883-1:2006 + Amd1:2014; ISO 17664:2017; ISO 17665-1:2006; ISO/TS 19930:2017; ISO 20857:2010; ISO/FDIS 25424:2018
3.167	**medical device manufacturer**	ISO 17664:2017
3.168	**method suitability**	ISO 11737-1:2018
3.169	**microbial barrier**	ISO/FDIS 11607-1:2018; ISO/FDIS 11607-2:2018
3.170	**microbial characterization**	ISO 11737-1:2018
3.171	**microbial contamination**	ISO 18362:2016
3.172	**microbial inactivation**	ISO 11138-1:2017; ISO/DIS 14160:2018; ISO 20857:2010
3.173	**microbial inactivation factor**	ISO/FDIS 15883-4:2018
3.174	**microbial reduction factor**	ISO 15883-1:2006 + Amd1:2014; ISO/FDIS 15883-4:2016
3.175	**microbial resistance**	ISO/FDIS 15883-4:2018
3.176	**microorganism**	ISO 11135:2014 + FDAmd 1; ISO 11137-1:2006 + Amd1:2013; ISO/TS 13004:2013; ISO 13408-2:2018; ISO 15883-1:2006 + Amd1:2014; ISO 17665-1:2006; ISO 18362:2016; ISO 20857:2010
3.177	**minimum effective concentration**	ISO/FDIS 15883-4:2018
3.178	**minimum recommended concentration**	ISO/FDIS 15883-4:2018
3.179	**moist heat**	ISO 17665-1:2006