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AMENDMENT 1

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

AMENDMENT 1: Amended and additional terms and definitions

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

AMENDEMENT 1: Termes et définitions modifiés et supplémentaires

PROOF/ÉPREUVE

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This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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AMENDMENT 1: Amended and additional terms and definitions

3.111 exposure phase

Replace the term and the text of the definition with the following:

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.

3.113.2 F_{BIO} value

Replace the text of the definition with the following:

3.113.2
F_{BIO} 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

Add the following new entry 3.113.4 $F_{BIOLOGICAL}$ value:

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.

3.133 holding time

Replace the text of the definition with the following:

3.133
holding time
period during which process or cycle parameters are maintained within their specified tolerances for defined cycle stages

Add the following new entry 3.133.1 holding time:

3.133.1
holding time
<moist heat sterilization> period for which the temperatures at the reference measurement point, and at all points within the load, are continuously within the sterilization temperature band

3.151 labelling

Replace the text of the definition with the following:

3.151
labelling
label, instructions for use and any other information related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents

[SOURCE: ISO 13485:2016, 3.8]

3.166 medical device

Added "in or on the human body" in the paragraph after the list, as follows:

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 which does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, 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.

