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Sterilization of health care products — Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities

Stérilisation des produits de santé — Exigences communes applicables aux stérilisateurs utilisés pour la stérilisation terminale des dispositifs médicaux dans les établissements de santé

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Foreword

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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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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 www.iso.org/iso/foreword.html.

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

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

A sterile health care product is one that is free of viable microorganisms. International Standards that specify requirements for validation and routine control of sterilization processes require, when it is necessary to supply a sterile health care product, that adventitious microbiological contamination of that health care product prior to sterilization be minimized. Even so, health care products produced under standard manufacturing conditions in accordance with the requirements for quality management systems (see, for example, ISO 13485) can, prior to sterilization, have microorganisms on them, albeit in low numbers. Such health care products are non-sterile. The purpose of sterilization is to inactivate or remove the microbiological contaminants and thereby transform the non-sterile health care products into sterile ones.

Conformance with the requirements of International Standards for development, validation and routine control of sterilization processes ensures that the sterilization process is both reliable and reproducible so that predictions can be made, with reasonable confidence, that there is a low probability of there being a viable microorganism present on a health care product after sterilization.

Exposure to a properly validated, accurately controlled sterilization process is not the only factor associated with the provision of reliable assurance that a processed medical device is sterile and, in this regard, suitable for its intended use. Attention is also given to a number of factors including:

a) the microbiological status of incoming raw materials or components;

b) the validation and routine control of any cleaning and disinfection procedures used on the medical device;

c) the control of the environment in which the medical device is manufactured, assembled and packaged;

d) the specified performance and maintenance of equipment;

e) the control of personnel and their hygiene;

f) the process and materials of the sterile barrier systems that are used to package the medical device;

g) the conditions under which the medical device is transported;

h) the conditions under which the medical device is stored.

The delivery of a validated and accurately controlled sterilization process is enabled by the use of sterilizing equipment that is designed, constructed, installed and qualified to deliver the sterilization process safely and reproducibly. This document defines common, general requirements that apply across a range of sterilizing equipment that can then be used:

1) as a template for future revisions of standards for sterilizing equipment for particular sterilization processes, and

2) to apply to equipment for which a particular standard does not exist.

This approach also provides opportunities not only to achieve a comprehensive and consistent set of global standards for sterilizing equipment but also to build on the work done in developing the existing standards for sterilizers at national and regional level to reach an international alignment on the requirements.

The verbal forms used in this document conform to the usage described in Clause 7 of the ISO/IEC Directives, Part 2:2018. For the purposes of this document, the auxiliary verb:

— "shall" means that conformance with a requirement or a test is mandatory for conformance with this document;

— "should" means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— "may" is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test); and

— "can" is used to express possibility and capability.

The conjunction "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The rationale for the requirements in this document has been provided in Annex A.