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Aseptic processing of health care products —

Part 5: Sterilization in place

Traitement aseptique des produits de santé —

Partie 5: Stérilisation sur place



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 13408-5 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO 13408 consists of the following parts, under the general title *Aseptic processing of health care products*:

- *Part 1: General requirements*
- *Part 2: Filtration*
- *Part 3: Lyophilization*
- *Part 4: Clean-in-place technologies*
- *Part 5: Sterilization in place*
- *Part 6: Isolator systems*

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Introduction

During the process of preparing ISO 13408-1, several items, e.g. filtration, freeze drying and sterilization in place, were found to be in need of supplementary information which was too voluminous to be given in corresponding annexes.

This part of ISO 13408 includes requirements and guidance that are to be observed during sterilization in place. The purpose of this part of ISO 13408 is to achieve standardization in the field of validation and routine control of sterilization in place processes used in the manufacture of health care products.

Sterilization in place is, in most instances, preceded by cleaning in place which is described in ISO 13408-4. While methods of cleaning in place and sterilization in place differ considerably in technology, the concept of *in situ* treatment is similar.

The most important issue to consider in establishing sterilization-in-place technology is the design of the system(s) to ensure that they be able to successfully sterilize manufacturing equipment to the desired level of sterility assurance.