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Aseptic processing of health care products —

Part 2: Filtration

*Traitement aseptique des produits de santé —
Partie 2: Filtration*



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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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.

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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 13408-2 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*

The following parts are under preparation:

— *Part 3: Freeze-drying*

— *Part 4: Sterilization in place*

— *Part 5: Cleaning in place*

— *Part 6: Isolator/barrier technology*

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Introduction

During the process of preparing ISO 13408-1:1998, which addresses general requirements, several items, e.g. filtration, freeze-drying and steam-in-place, were found to be in need of supplementary information which was too large to be given in corresponding Annexes. This part of ISO 13408 includes requirements and guidance that are to be observed when aseptically manufacturing health care products by filtration.

ISO 13408-1:1998 will be revised soon after the publication of this part of ISO 13408, as clause 20 of ISO 13408-1:1998 is replaced by this part of ISO 13408.