
**Aseptic processing of health care
products —**

**Part 2:
Filtration**

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



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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 13408-2 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*

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.

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Aseptic processing of health care products —

Part 2: Filtration

1 Scope

This part of ISO 13408 specifies requirements for sterilizing filtration as part of aseptic processing of health care products. It also offers guidance to filter users concerning general requirements for set-up, validation and routine operation of a sterilizing filtration process, to be used for aseptic processing of health care products.

This part of ISO 13408 is not applicable to removal of viruses. Sterilizing filtration is not applicable to fluids containing particles as effective ingredient larger than the pore size of a filter (e.g. bacterial whole-cell vaccines).

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13408-1:1998, *Aseptic processing of health care products — Part 1: General requirements*

ISO/TS 11139:2001, *Sterilization of health care products — Vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13408-1, ISO/TS 11139 and the following apply.

3.1

bacterial challenge test

test to evaluate the capability of a filter to retain organisms from a bacterial suspension under defined conditions

3.2

bioburden

population of viable microorganisms in a fluid prior to sterilizing filtration

NOTE For the purposes of this part of ISO 13408, the definition of bioburden is narrower than that in ISO/TS 11139.

3.3

chemical compatibility

ability of the process fluids not to adversely affect the properties of filter materials and/or filter assembly components and vice versa

3.4

fibre

particle having an aspect (length-to-width) ratio of 10 or more

[ISO 14644-1:1999, 2.2.7]