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Aseptic processing of health care products —

Part 6: Isolator systems

Traitement aseptique des produits de santé —

Partie 6: Systèmes isolateurs



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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 13408-6 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

Health care products that are labelled “sterile” are prepared by using appropriate and validated methods. When a health care product is intended to be sterile and cannot be terminally sterilized, aseptic processing provides an alternative. This applies to the aseptic preparation and filling of solutions, suspensions, emulsions, and solids, as well as to the aseptic handling, transfer and filling of those products which cannot be terminally sterilized.

Aseptic processing is an exacting and demanding discipline. It is essential that manufacturers make use of qualified/validated systems, adequately trained personnel, controlled environments and well-documented systematic processes to assure a sterile finished product.