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Aseptic processing of health care products —

Part 7: Alternative processes for medical devices and combination products

Traitement aseptique des produits de santé —

Partie 7: Procédés alternatifs pour les dispositifs médicaux et les produits de combinaison

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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 13408-7 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*

— *Part 7: Alternative processes for medical devices and combination products*

Introduction

ISO 13408 is the International Standard, published in a series of parts, for aseptic processing of health care products. Historically, sterile health care products that are aseptically produced have typically been liquids, powders or suspensions that cannot be terminally sterilized. More recently, medical devices and health care products have been developed that are combined with medicinal products, including biological and viable cells, that cannot be terminally sterilized.

The application of ISO 13408-1 to these medical devices and combination products can require the development of alternative approaches to process simulation. This part of ISO 13408 specifies requirements and provides guidance for developing such alternative approaches for the qualification of aseptic processes through process simulation of medical devices and combination products that meet the requirements of ISO 13408-1.

ISO 13408-1:2008, 10.1.2 permits the use of alternative process simulation approaches, based on particular medical devices or combination products, where the substitution in full with sterile liquid media might not be possible.

Medical devices and combination products that typically require aseptic processing might include, for example, the following.

a) Medical devices that cannot be terminally sterilized and where the process simulation approach according to ISO 13408-1 cannot be applied:

   — bioprostheses (e.g. heart valves, vascular implants);

   — biodegradable implants (e.g. hernia meshes);

   — artificial and/or non-viable biologically based matrixes;

   — extracorporeal processing devices (e.g. immuno-adsorbers);

   — implantable osmotic pumps;

   — hermetically sealed electromechanical devices and partially enclosed electronic devices (e.g. invasive and non-invasive diagnostic devices).

b) Combination products (including viable cell-based combination products):

   — implants coated with drug and/or biologically derived substances (e.g. drug-coated stents, carrier materials with protein, bone-graft material with growth factors, biodegradable drug-coated stents);

   — wound dressings (e.g. dressings with haemostatic agents, tissue sealants, or biologics);

   — transdermal or injectable delivery systems (e.g. drug-coated or biologics interstitial patches);

   — kits containing a biological or drug component (e.g. demineralized bone matrices).

For such products, a risk management strategy and method(s) can be used for the identification, evaluation and quantification (estimation) of contamination risks throughout the entire product/process life cycle. Environmental monitoring and microbiological studies can be performed on individual steps of the process to evaluate the effectiveness of contamination controls and risk mitigations. The design of the process simulation can then be driven by the results of the risk analysis. If the results of the process simulation are acceptable, this provides evidence that the aseptic process is in a state of contamination control (i.e. no extrinsic microbiological/microbial contamination has been introduced during the aseptic process).

This part of ISO 13408 should be read in conjunction with ISO 13408-1.

Within this International Standard, text that supplements ISO 13408-1 by providing additional requirements or guidance is identified by the prefix “Addition”.