INTERNATIONAL STANDARD

ISO 13683

First edition
1997-05-15

Sterilization of health care products — Requirements for validation and routine control of moist heat sterilization in health care facilities

Stérilisation des produits de santé — Exigences pour la validation et le contrôle pratique de la stérilisation en chaleur humide dans les locaux de soins de santé

Reference number
ISO 13683:1997(E)

This is a preview. Click here to purchase the full publication.

Contents

© ISO 1997

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet central@iso.ch
X.400 c=ch; a=400net; p=iso; o=isocs; s=central

Printed in Switzerland

This is a preview. Click here to purchase the full publication.

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.

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.

International Standard ISO 13683 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

Annexes A, B and C of this International Standard are for information only.

This is a preview. Click here to purchase the full publication.

Introduction

Persons having responsibility for safe sterile health care products should be aware of available sterilization processes, methods of control, and physical characteristics of the product to be sterilized. Products produced under controlled conditions will have microorganisms on them and are, by definition, non-sterile. The purpose of sterilization is to destroy these microbiological contaminants. After sterilization, however, there is always a finite probability that a microorganism could survive regardless of the treatment applied. As a consequence, sterility of a processed item is defined in terms of the probability of the occurrence of a single viable microorganism surviving on the item.

Requirements for a quality system for the design, development, production, supply, installation and servicing of health care products are given in the ISO 9000 series of standards.

The ISO 9000 series of standards designates certain processes used in the manufacture of health care products as "special" in that the result cannot be fully verified by subsequent inspection or testing of the product. Sterilization is an example of a special process, because efficacy cannot be verified by inspection or testing of the product. For this reason, sterilization processes must be validated before use, the process routinely monitored and the equipment maintained.

This is a preview. Click here to purchase the full publication.

Sterilization of health care products — Requirements for validation and routine control of moist heat sterilization in health care facilities

1 Scope

1.1 Inclusions

1.1.1 This International Standard specifies requirements for the use of moist heat in sterilization process development, validation of the sterilization process, and control of routine sterilization in either a health care facility or a facility contracted by a health care organization.

1.1.2 This International Standard covers all moist heat processes in health care facilities in which the sterilant is either steam, steam/air mixtures or pressurized water.

NOTE — While the general requirements of this International Standard can apply to the sterilization of pharmaceutical products, other technical or regulatory requirements may also apply.

1.2 Exclusions

1.2.1 This International Standard does not describe a quality assurance system for the control of all stages of production.

NOTE — Attention is drawn to the International Standards for quality systems (ISO 13485 or ISO 13488) which control all stages of production including the sterilization process. It is not a requirement of this International Standard to have a complete quality system during production, but certain elements of such a system are required and these are normatively referenced at appropriate places in the text.

1.2.2 Except for general requirements, this International Standard does not provide detailed requirements for all equipment used within a sterilization system (e.g. washing equipment).

1.2.3 This International Standard does not address sterilization processes that employ a chemical/steam mixture as the sterilant.

1.2.4 This International Standard does not apply to industrial moist heat sterilization, which is addressed by ISO 11134.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing.*

This is a preview. Click here to purchase the full publication.