INTERNATIONAL STANDARD

ISO 15882

First edition
2003-03-15

Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results

Stérilisation des produits de santé — Indicateurs chimiques — Lignes directrices pour le choix, l'emploi et l'interprétation des résultats

Reference number
ISO 15882:2003(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

ISO copyright office
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

Published in Switzerland

Contents

Page

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 15882 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products.*

Introduction

Performance requirements for manufacturers of chemical indicators are contained in the ISO 11140 series. This International Standard provides guidance regarding the selection, use and interpretation of results of chemical indicators used to monitor sterilization processes employing steam, ethylene oxide, γ- or β-radiation, steam-formaldehyde, or dry heat as documented in ISO 11140-1:1995 (amended 1998). The procedures described in this International Standard are of a general nature and do not, of themselves, constitute a comprehensive monitoring programme with regard to the sterilization of health care products. The intent of this International Standard is not to mandate the use of chemical indicators in a process, but to provide guidance for their proper selection and use. National standards should be consulted for information on the use of chemical indicators as well as the frequency of their use.

The complexity of modern medical technology and the wide variety of sterilization processing techniques and equipment available have made effective sterility assurance programmes more challenging than ever before. The need for convenient, inexpensive and rapid means of detecting sterilization problems has brought about the development of sterilization process monitors generally referred to as “chemical indicators”. In this International Standard, users will find guidance on selection of the correct chemical indicator for their particular sterilization process and critical parameters, e.g. the choice of an appropriate chemical indicator, as well as guidance on its appropriate use.

Harmonization of the International and European standards on chemical indicators, ISO 11140 and EN 867, is in progress.

Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results

1 Scope

This International Standard provides guidance for the selection, use and interpretation of results of chemical indicators used in process definition, validation, and routine monitoring and control of sterilization processes. This International Standard is applicable to chemical indicators for which International Standards exist (see ISO 11140 series).

This International Standard is not applicable to those processes that rely on physical removal of microorganisms, e.g. filtration.

This International Standard is not intended to apply to combination processes, for example, washer-disinfectors or flushing and steaming of pipelines.

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 11138-2:1994, *Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization*

ISO 11138-3:1994, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization*

ISO 11140-1, *Sterilization of health care products — Chemical Indicators — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
endpoint
observable change specified by the manufacturer that occurs after the indicator has been exposed to certain predefined physical conditions

3.2
chemical indicator
system that reveals a change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process

3.3
critical parameter
parameter identified as being essential to the sterilization process (and requiring monitoring)