INTERNATIONAL STANDARD

ISO 15882

Second edition
2008-09-01

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

Stérilisation des produits de santé — Indicateurs chimiques — Directives pour la sélection, l'utilisation et l'interprétation des résultats

Reference number
ISO 15882:2008(E)

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

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

This second edition cancels and replaces the first edition (ISO 15882:2003) which has been technically revised.

Introduction

This International Standard provides guidance for users regarding the selection, use and interpretation of results of chemical indicators intended for use with sterilization processes employing steam, dry heat, ethylene oxide, γ or β radiation, low temperature steam and formaldehyde (LTSF), or vapourized hydrogen peroxide as documented in ISO 11140-1 [13]. The ISO 11140 [12], [13], [14], [15], [16] series of standards specifies performance requirements for chemical indicators. These standards are intended primarily for the use of manufacturers of chemical indicators. The guidance in this document is of a general nature; chemical indicators do not, of themselves, constitute a comprehensive monitoring programme with regard to the sterilization of health care products. Users' attention is drawn to the requirements for validation of sterilization processes specified in ISO 14937 [18] for general processes, the ISO 17665 [19], [20] series for moist heat sterilization, the ISO 11135 [5], [6] series for ethylene oxide sterilization, ISO 11137-1 [7] for radiation sterilization and ISO 20857 [22] for dry heat sterilization.

The actual use/frequency of chemical indicators might be regulated by international and or national standards as well as by local regulatory authorities.

The need for convenient and rapid means of detecting sterilization problems occurring during sterilization processes 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 as well as guidance on its appropriate 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.

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

1 Scope

1.1 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 overall control of sterilization processes. This International Standard applies to indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances, and which are used to monitor one or more of the variables required of a sterilization process. These chemical indicators are not dependent for their action on the presence or absence of a living organism.

1.2 This International Standard does not consider indicators for use in those processes that rely on physical removal of microorganisms, e.g. filtration.

1.3 This International Standard is not intended to apply to indicators for use in combination processes, for example, washer disinfectors or CIP (cleaning in place) and SIP (sterilization in place).

2 Terms and definitions

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

NOTE A vocabulary of terms used for sterilization of health care products is provided in ISO/TS 11139[11].

2.1
chemical indicator
non-biological indicator
test system that reveals change in one or more pre-defined process variables based on a chemical or physical change resulting from exposure to a process

[ISO/TS 11139, definition 2.6]

2.2
endpoint
point of the observed change as defined by the manufacturer occurring after the indicator has been exposed to specified stated values

[ISO 11140-1, definition 3.3]

2.3
indicator
combination of the indicator agent and its substrate in the final form in which it is intended to be used

[ISO 11140-1 definition 3.5]

NOTE 1 An indicator system in combination with a specific test load is also termed an indicator.

NOTE 2 See Annex E.