
**Sterilization of health care products —
Chemical indicators —**

**Part 1:
General requirements**

*Stérilisation des produits de santé — Indicateurs chimiques —
Partie 1: Exigences générales*

Sample Document

get full document from standards.iteh.ai



Sample Document

get full document from standards.iteh.ai



COPYRIGHT PROTECTED DOCUMENT

© ISO 2014

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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..... | v |
| Introduction..... | vi |
| 1 Scope..... | 1 |
| 2 Normative references..... | 1 |
| 3 Terms and definitions..... | 2 |
| 4 Categorization..... | 4 |
| 4.1 General..... | 4 |
| 4.2 Type 1: process indicators..... | 4 |
| 4.3 Type 2: indicators for use in specific tests..... | 5 |
| 4.4 Type 3: single critical process variable indicators..... | 5 |
| 4.5 Type 4: multicritical process variable indicators..... | 5 |
| 4.6 Type 5: integrating indicators..... | 5 |
| 4.7 Type 6: emulating indicators..... | 5 |
| 5 General requirements..... | 5 |
| 6 Performance requirements..... | 8 |
| 6.1 General..... | 8 |
| 6.2 Type 1 indicators..... | 9 |
| 6.3 Type 2 indicators..... | 9 |
| 6.4 Types 3, 4, 5 and 6 indicators..... | 9 |
| 7 Test methods..... | 9 |
| 7.1 General..... | 9 |
| 7.2 Off-set (transference)..... | 9 |
| 7.3 Procedure — Steam indicators..... | 9 |
| 7.4 Procedure — Dry heat indicators..... | 10 |
| 7.5 Procedure — EO indicators..... | 10 |
| 7.6 Procedure — Low temperature steam and formaldehyde indicators..... | 11 |
| 7.7 Procedure — Vaporized hydrogen peroxide indicators..... | 11 |
| 8 Additional requirements for process (Type 1) indicators..... | 12 |
| 8.1 Process indicators printed or applied on to packaging material..... | 12 |
| 8.2 Process indicators for steam sterilization processes..... | 12 |
| 8.3 Process indicators for dry heat sterilization processes..... | 12 |
| 8.4 Process indicators for ethylene oxide sterilization processes..... | 13 |
| 8.5 Process indicators for radiation sterilization processes..... | 13 |
| 8.6 Process indicators for low temperature steam and formaldehyde sterilization processes..... | 14 |
| 8.7 Process indicators for vaporized hydrogen peroxide sterilization processes..... | 14 |
| 9 Additional requirements for single critical process variable (Type 3) indicators..... | 15 |
| 10 Additional requirements for multicritical process variable (Type 4) indicators..... | 15 |
| 11 Additional requirements for steam integrating (Type 5) indicators..... | 16 |
| 12 Additional requirements for ethylene oxide integrating (Type 5) indicators..... | 17 |
| 13 Additional requirements for emulating (Type 6) indicators..... | 17 |
| Annex A (normative) Method for demonstrating shelf-life of the product..... | 19 |
| Annex B (informative) Examples of testing indicators..... | 20 |
| Annex C (informative) Rationale for the requirements for integrating indicators and the link to the requirements for biological indicators specified in ISO 11138 (all parts) and microbial inactivation..... | 22 |
| Annex D (informative) Rationale for the liquid-phase test method for low temperature steam and | |

| | |
|--|-----------|
| formaldehyde indicators | 29 |
| Annex E (informative) Relationship of indicator and indicator system components | 30 |
| Bibliography | 31 |

Sample Document

get full document from standards.iteh.ai

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 198, *Sterilization of health care products*.

This third edition cancels and replaces the second edition (ISO 11140-1:2005), which has been technically revised.

ISO 11140 consists of the following parts, under the general title *Sterilization of health care products — Chemical indicators*:

- *Part 1: General requirements*
- *Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test*
- *Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration*
- *Part 5: Class 2 indicators for Bowie and Dick-type air removal tests*

ISO 11140-2 has been withdrawn and replaced by ISO 18472.

Introduction

This part of ISO 11140 specifies performance requirements and/or test methods for chemical indicators intended for use with sterilization processes employing steam, dry heat, ethylene oxide, γ or β radiation, low temperature steam and formaldehyde or vaporized hydrogen peroxide.

Additional requirements for indicators intended for use with other sterilization methods (e.g. other forms of moist heat sterilization) are not specifically provided in this part of ISO 11140; however, the general requirements will apply.

The requirements for specific test indicators (e.g. Bowie-Dick test indicators and indicator systems) are covered in other parts of ISO 11140.

Standards for sterilizers and for the validation and process control of sterilization describe performance tests for sterilizers and methods of validation and routine control, respectively.

This part of ISO 11140 is intended for manufacturers of chemical indicators and specifies the general requirements for chemical indicators. The categorization structure for chemical indicators is used solely to denote the characteristics and intended use of each type of indicator when used as specified by the manufacturer. This categorization has no hierarchical significance. The chemical indicators described in this part of ISO 11140 are categorized into six types. The chemical indicators within each of these categorizations are further subdivided by the sterilization process for which they are designed to be used. This part of ISO 11140 defines the requirements for Type 1 and Types 3 to 6. In subsequent parts of ISO 11140, the requirements for Type 2 indicators are categorized by their intended use. The use of the indicators and indicator systems, specified in this part of ISO 11140, is described in for example the ISO 11135, the ISO 17665- series, ISO 15882, EN 285, and EN 13060.

Resistometers are used to characterize the performance of the chemical indicators described in this part of ISO 11140, with the exception of Type 2 indicators. Requirements for resistometers are specified in ISO 18472. Resistometers differ from sterilizers. As sterilizers cannot duplicate resistometer conditions they should not be used to test the performance of chemical indicators. Sterilizers from different manufacturers and of different ages have significantly different cycle profiles; for example, prolonged preconditioning phases. Resistometers allow for precise control of the specific test cycle sequences in order to study the effect of process parameters on indicator performance under controlled, repeatable conditions. Guidance on the selection, use and interpretation of the results of chemical indicators is given in ISO 15882. Users of chemical indicators are expected to make reference to this part of ISO 11140.

Sterilization of health care products — Chemical indicators —

Part 1: General requirements

WARNING — The use of this part of ISO 11140 can involve hazardous materials, operations and equipment. This part of ISO 11140 does not purport to address all of the safety problems associated with their use. It is the responsibility of the user of this part of ISO 11140 to determine the applicability of national or regional regulatory requirements and to establish appropriate occupational health and safety practices prior to use of any hazardous materials, operations and/or equipment.

1 Scope

This part of ISO 11140 specifies general requirements and test methods for indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances, and which are used to monitor the attainment of one or more of the process parameter(s) specified for a sterilization process. They are not dependent for their action on the presence or absence of a living organism.

NOTE 1 Biological test systems are regarded as those test systems which are dependent for their interpretation on the demonstration of the viability of an organism. Test systems of this type are considered in the ISO 11138-series for biological indicators (BIs).

The requirements and test methods of this part of ISO 11140 apply to all indicators specified in subsequent parts of ISO 11140, unless the requirement is modified or added to by a subsequent part, in which case the requirement of that particular part will apply.

Relevant test equipment is described in ISO 18472.

NOTE 2 Additional requirements for specific test indicators/indicator systems (Type 2 indicators) are given in ISO 11140-3, ISO 11140-4 and ISO 11140-5.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8601:2004, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 11135:2014, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1:2006, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2:2013, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11137-3:2006, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects*

ISO 11140-1:2014(E)

ISO 11138-1:2006, *Sterilization of health care products — Biological indicators — Part 1: General requirements*

ISO 11138-2:2006, *Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes*

ISO 11138-3:2006, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes*

ISO 11138-4:2006, *Sterilization of health care products — Biological indicators — Part 4: Biological indicators for dry heat sterilization processes*

ISO 11138-5:2006, *Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes*

ISO 11140-3:2007, *Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test*

ISO 11140-4:2007, *Sterilization of health care products — Chemical indicators — Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration*

ISO 11140-5:2007, *Sterilization of health care products — Chemical indicators — Part 5: Class 2 indicators for Bowie and Dick-type air removal tests*

ISO 17665-1:2006, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO/TS 17665-2:2009, *Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1*

ISO/TS 17665-3:2013, *Sterilization of health care products — Moist heat — Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization*

ISO 18472:2006, *Sterilization of health care products — Biological and chemical indicators — Test equipment*

3 Terms and definitions

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

3.1

bleed

unintentional lateral migration of the indicator agent beyond the margins within which the indicator agent was applied

3.2

critical process variable

variable identified as being essential to the attainment of sterilization and monitored by the chemical indicator

3.3

endpoint

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

3.4

exposure period

time from the attainment of the specified exposure conditions to its termination

3.5**graduated response**

progressive observable change occurring on exposure to one or more critical process variables allowing assessment of the level achieved

3.6**indicator**

combination of the indicator agent and its substrate that reveals change in one or more process variables based on a chemical or physical change resulting from exposure to a process

Note 1 to entry: An indicator intended to be used only in combination with a specific test load is also termed an indicator (both together becoming an indicator system).

Note 2 to entry: See [Annex E](#).

3.7**indicator agent**

active substance(s) or combination of substances

Note 1 to entry: See [Annex E](#).

3.8**indicator system**

combination of an indicator and a specific test load

3.9**off-set**

transfer of indicator agent to a material in intimate contact with the surface of the indicator

3.10**process parameter**

specified value for a critical process variable

Note 1 to entry: The specification for a sterilization process includes the process parameters and their tolerances.

[SOURCE: ISO/TS 11139:2006, 2.34]

3.11**saturated steam**

water vapour in a state of equilibrium between condensation and evaporation

3.12**stated value****SV**

value or values of a critical process variable at which the indicator is designed to reach its endpoint as defined by the manufacturer

3.13**substrate**

carrier or support material on to which the indicator agent is applied

Note 1 to entry: See [Annex E](#).

3.14**visible change**

change defined by the manufacturer, which can be seen in Type 1 indicators after exposure to one or more critical process variables of the process