INTERNATIONAL STANDARD

ISO 11140-1

Second edition
2005-07-15

Sterilization of health care products — Chemical indicators —

Part 1: General requirements

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

Reference number
ISO 11140-1:2005(E)

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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 11140-1 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11140-1:1995 and ISO 11140-1:1995/Amd.1:1998), 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 2: Test equipment and methods*

— *Part 3: Class 2 indicators for steam penetration test sheets*

— *Part 4: Class 2 indicators for steam penetration test packs*

— *Part 5: Class 2 indicators for air removal test sheets and packs*

NOTE ISO 11140-2 is to be replaced by ISO 18472, *Sterilization of health care products — Biological and chemical indicators — Test equipment.*

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, steam-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) 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. Subsequent parts of this International Standard specify the particular requirements for chemical indicators for particular applications and for defined tests of particular sterilization processes used in health care, including industry. The use of the indicators specified in this part of ISO 11140 are described in ISO 15882, EN 285, ISO 11135 and ISO 17665.

Resistometers (see ISO 18472) are used to characterize the performance of the chemical indicators described in this part of ISO 11140. Resistometers allow for precise variation of the specific test conditions and cycle sequences in order to produce controlled physical studies. Resistometers differ from conventional sterilizers; therefore, if conventional sterilizers are used to attempt to duplicate resistometer conditions, erroneous and/or misleading results may occur.

Sterilization of health care products — Chemical indicators —

Part 1: General requirements

WARNING — The use of this part of ISO 11140 may involve hazardous materials, operations and equipment. This part of ISO 11140 does not purport to address to all the safety problems associated with its use. It is the responsibility of the user of this part of ISO 11140 to establish appropriate safety and health practise and determine the applicability of regulatory limitations prior to use.

1 Scope

1.1 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 variables required for a sterilization process. They are not dependent for their action on the presence or absence of a living organism.

NOTE Biological test systems are regarded as those tests 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).

1.2 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 Additional requirements for specific test indicators (Class 2 indicators) are given in ISO 11140-3, ISO 11140-4 and ISO 11140-5.

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

ISO 11138 (all parts), *Sterilization of health care products — Biological indicator systems*

ISO 11607, *Packaging for terminally sterilized medical devices*

ISO 18472[1)], *Sterilization of health care products — Biological and chemical indicators — Test equipment*

1) To be published.

3 Terms and definitions

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

3.1
bleed
lateral migration of the indicator agent beyond the margins within which the indicator agent was applied

3.2
critical variable
parameters identified as being essential to the sterilization process (and requiring monitoring)

3.3
endpoint
point of the observed change as defined by the manufacturer occurring after the indicator has been exposed to specified stated values

3.4
graduated response
progressive observable change occurring on exposure to one or more process variables allowing assessment of the level achieved

3.5
indicator
combination of the indicator agent and its substrate in the final form in which it is intended to be used (see Annex E)

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

3.6
indicator agent/indicator reagent
active substance(s) or combination of substances (see Annex E)

3.7
indicator system
combination of the indicator agent and its substrate subsequently intended to be used in combination with a specific test load

3.8
off-set
transfer of indicator agent to a material in intimate contact with the surface of the indicator

3.9
parameter
specified value for a process variable

3.10
penetration
migration of the indicator agent through the substrate to the surface opposite the one to which the indicator agent was applied

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 variable at which the indicator is designed to reach its endpoint as defined by the manufacturer

3.13
substrate
carrier or support material onto which the indicator is applied (see Annex E)

3.14
variable
condition within a sterilization process, changes that alter microbicidal effectiveness

3.15
visible change
change defined by the manufacturer, which can be seen in the indicator after exposure to one or more critical variables of the process

NOTE Visible change is used to describe the response of Class 1 process indicators.

4 Classification

4.1 General

In subsequent parts of ISO 11140, indicators are classified by their intended use. The chemical indicators described in this part of ISO 11140 are classified into six groups. The chemical indicators within each of these classifications are further subdivided by the sterilization process for which they are designed to be used. The classification structure used is solely to denote the characteristics and intended use of each type of indicator when used as defined by the manufacturer. This classification has no hierarchical significance.

4.2 Class 1: process indicators

Process indicators are intended for use with individual units (e.g. packs, containers) to indicate that the unit has been directly exposed to the sterilization process and to distinguish between processed and unprocessed units. They shall be designed to react to one or more of the critical process variables (see Tables 1 to 6).

4.3 Class 2: indicators for use in specific tests

Class 2 indicators are intended for use in specific test procedures as defined in relevant sterilizer/sterilization standards.

NOTE The requirements for specific test indicators (Class 2 indicators) are provided in other parts of ISO 11140.

4.4 Class 3: single variable indicators

A single variable indicator shall be designed to react to one of the critical variables (see 5.2) and is intended to indicate exposure to a sterilization process at a stated value (SV) of the chosen variable (see 5.7 and 5.8).

4.5 Class 4: multi-variable indicators

A multi-variable indicator shall be designed to react to two or more of the critical variables (see 5.2) and is intended to indicate exposure to a sterilization cycle at SVs of the chosen variables (see 5.7 and 5.8).

4.6 Class 5: integrating indicators

Integrating indicators shall be designed to react to all critical variables. The SVs are generated to be equivalent to, or exceed the performance requirements given in the ISO 11138 series for BIs (see Clauses 11, 12 and 13).

4.7 Class 6: emulating indicators

Emulating indicators are cycle verification indicators which shall be designed to react to all critical variables for specified sterilization cycles. The SVs are generated from the critical variables of the specified sterilization process.

5 General requirements

5.1 The requirements given in this clause shall apply to all indicators unless specifically excluded or amended in a subsequent clause or part of ISO 11140.

5.2 For the different sterilization processes, the following variables are defined as being critical:

- STEAM — Time, temperature and water (as delivered by saturated steam)
- DRY HEAT — Time and temperature
- ETHYLENE OXIDE — Time, temperature, relative humidity and ethylene oxide (EO) concentration
- IRRADIATION — Total absorbed dose
- STEAM-FORMALDEHYDE — Time, temperature, water (as delivered by saturated steam) and formaldehyde concentration
- VAPOURIZED HYDROGEN PEROXIDE — Time, temperature, hydrogen peroxide concentration, and, if applicable, plasma

5.3 The manufacturer shall establish, document and maintain a formal quality system to cover all operations required by this part of ISO 11140.

NOTE ISO 9001 and ISO 13485 describe requirements for quality systems for design, manufacture and testing.

5.4 Each indicator shall be clearly marked with the type of process for which it is intended to be used (see 5.6 and 5.7), with the the class of indicator (see Clause 4), and for Class 3, 4, 5 and 6 indicators, with the the SVs.

Where the size or format of the indicator does not permit this information to be stated in a font of 6 characters per centimetre or larger, the information shall be provided on the label and/or instructions for use.

5.5 The indicator shall comply with the requirements of this part of ISO 11140 for the duration of the shelf life as specified by the manufacturer (see Annex A).

5.6 Abbreviated descriptions of the process shall be in accordance with the following symbols:

STEAM

— all steam sterilization processes

DRY

— all dry heat sterilization processes

EO

— all ethylene oxide sterilization processes

IRRAD

— all ionizing radiation sterilization processes

FORM

— all steam/formaldehyde sterilization processes

VH2O2

— all vaporized hydrogen peroxide sterilization processes

These descriptions are symbols and should not be translated.

5.7 If the indicator is designed for use in specific sterilization cycles, this information shall be stated or coded on the indicator, e.g.

STEAM

121 °C 15 min

(See 3.12 and 5.6.)

5.8 Each package of indicators or the technical information leaflet supplied with the package shall provide the following information:

a) the change that is intended to occur; and for colour change indicators where the colour change cannot be adequately described, samples of the expected colour range for both changed and unchanged indicators;

b) the critical variable(s) to which the indicator will respond, and where applicable, their SVs;

c) the class (see Clause 4), process (see 5.6) and intended use (see 5.7) for which the indicator is designed;

d) the storage conditions, before and after use;

e) the expiry date, or the manufacturing date plus shelf life, under the specified storage conditions, expressed in accordance with ISO 8601 (e.g. YYYY-MM);

f) a unique code (e.g. lot number) to provide traceability;

g) instructions for use essential to ensure proper functioning of the indicator;

h) any interfering substances that are likely to be encountered, or conditions that are likely to occur, during the intended use of the indicator and which are known to affect adversely the performance of the indicator;

i) any safety precautions required during and/or after use;

j) the manufacturer's or supplier's name and address;

k) the nature of any change that can occur when completely/incompletely changed indicators are stored according to the manufacturer's instructions.

NOTE National or regional regulations could contain additional or different requirements.

5.9 The manufacturer shall retain documentary evidence that the indicator, when used as intended by the manufacturer, does not release any substance known to be toxic in sufficient quantities to cause either a health hazard, or a hazard to the intended properties of the product being sterilized before, during or after the sterilization process for which it is designated.

6 Performance requirements

6.1 General

6.1.1 The condition of the indicator after exposure to a sterilization process, during which all the variables met or exceeded the specified level to produce a visible change, graduated response or endpoint, shall remain unchanged for a period of not less than six months from the date of use, when stored under the conditions specified by the indicator manufacturer.

6.1.2 Incompletely changed indicators can deteriorate on storage, either returning to the unchanged condition or slowly completing the change reaction. If such deterioration can occur, this information should be stated in the technical information supplied by the manufacturer [see 5.8 k)].

6.2 Class 1 Indicators

6.2.1 The visible change that occurs after exposure of the indicator shall be clearly observable and shall be either from light to dark, dark to light, or shall be from one colour to a distinctly different colour (see Clause 8).

6.2.2 When printed on to single-use packaging material complying with ISO 11607, the indicator agent shall not bleed or offset to such an extent that it compromises the utility of the indicator or presents a hazard for the use of the packaging material. Penetration shall not occur before, during or after the sterilization process for which it is designed, when tested according to the method given in 7.2 (see also 5.9).

6.3 Class 2 indicators

Specific requirements for Class 2 indicators are given in Parts 3, 4 and 5 of ISO 11140.

6.4 Classes 3, 4, 5 and 6 indicators

6.4.1 The endpoint which occurs after exposure of the indicator to the SVs of critical variables shall be clearly observable and shall be either from light to dark, dark to light or shall be from one colour to a distinctly different colour.

6.4.2 The indicator agent shall not off-set or penetrate the substrate to which it is applied, or materials with which it is in contact before, during or after the sterilization process for which it is designed, when tested according to the method given in 7.2 (see also 5.9).

