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NSAI Standards

Irish Standard
I.S. EN ISO 11139:2018&LC:2018

Sterilization of health care products - Vocabulary of terms used in sterilization and related equipment and process standards (ISO 11139:2018)

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I.S. EN ISO 11139:2018&LC:2018

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National Foreword

I.S. EN ISO 11139:2018&LC:2018 is the adopted Irish version of the European Document EN ISO 11139:2018, Sterilization of health care products - Vocabulary of terms used in sterilization and related equipment and process standards (ISO 11139:2018)

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Correction Notice

Reference: **EN ISO 11139:2018**

Title: Sterilization of health care products - Vocabulary - Terms used in sterilization and related equipment and process standards (ISO 11139:2018)

Work Item: 00102124

Brussels, 2018-09-26

Please include the following minor editorial correction(s) in the document related to:

the following language version(s) :

- ☒ English
- ☐ French
- ☐ German

for the following procedure :

- ☐ PQ/UQ
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- ☐ 2nd Parallel Formal Vote
- ☐ UAP
- ☐ TC Approval
- ☐ 2nd TC Approval
- ☐ Publication
- ☒ Parallel Publication

It has been brought to our attention that this document, issued on 2018-09-12, requires modification.

Insertion of special foreword as requested by the TC

Please find enclosed the updated English version.

We apologise for any inconvenience this may cause.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11139

September 2018

ICS 01.040.11; 11.080.01

English Version

Sterilization of health care products - Vocabulary of terms used in sterilization and related equipment and process standards (ISO 11139:2018)

Stérilisation des produits de santé - Vocabulaire des termes utilisés dans les normes de procédés de stérilisation et les équipements connexes (ISO 11139:2018)

Sterilisation von Produkten für die Gesundheitsfürsorge - Vokabular, das bei der Sterilisation und zugehöriger Ausrüstung sowie in Prozessnormen verwendet wird (ISO 11139:2018)

This European Standard was approved by CEN on 1 September 2018.

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Ref. No. EN ISO 11139:2018 E

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European foreword

This document (EN ISO 11139:2018) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2019, and conflicting national standards shall be withdrawn at the latest by March 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

According to CEN Internal Regulations, terms and definition are always developed for a specific subject of the relevant standard/specification of the relevant working group. The working group uses the advice of the terminology working group to ensure that new terms and definitions are in line with the regulations and not in conflict with existing terms and definitions. Whenever possible, terms and definitions can be taken form the terminology standard EN ISO 11139.

ISO 11139 mentions a „White Paper“ in the ISO Foreword. CEN does not endorse this „White Paper“ for the following reasons:

— there was no official standardisation request for the preparation of such a document,

— the document has not been developed according to CEN Internal Regulations and

— the document is outside the scope of EN ISO 11139.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11139:2018 has been approved by CEN as EN ISO 11139:2018 without any modification.

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INTERNATIONAL STANDARD

ISO 11139

First edition
2018-08

Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards

Stérilisation des produits de santé — Vocabulaire des termes utilisés dans les normes de procédés de stérilisation et les équipements connexes

Reference number
ISO 11139:2018(E)

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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.

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 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

This first edition of ISO 11139 cancels and replaces ISO/TS 11139:2006, which has been technically revised.

The main changes compared with the previous edition are as follows:

— all the terms and definitions have been reviewed based on existing documents in the field and future needs, and have been revised accordingly for consistency of use;

NOTE This vocabulary is now the source document for these terms.

— additional terms and definitions have been added.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

This document provides the fundamental vocabulary for sterilization of health care products and associated equipment. It provides the foundation for other standards on cleaning, disinfecting, sterilizing, and aseptic processing of health care products together with associated equipment and ancillary products used in ensuring effective application of these processes. This document is intended to help the user to understand the vocabulary of cleaning, disinfecting, sterilizing, and aseptically processing health care products, in order to be able to implement the related standards effectively.

This document contains the terms and definitions that apply to all standards on cleaning, disinfecting, sterilizing, and aseptic processing of health care products together with associated equipment and ancillary products developed by ISO/TC 198 and other European standards in the same field of application.

The terms and definitions are arranged in alphabetical order in English.

ISO/TC 198 has produced a white paper describing the principles used to develop this compilation of terms and definitions and proposals on its use in the development of new and revised standards for disinfecting, sterilizing, and aseptic processing of health care products together with associated equipment and ancillary products. This white paper is available through the International Organization for Standardization.

The Bibliography includes the standards referenced in Annex A. If a term has been dropped in a current revision, reference has not been made.

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Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards

1 Scope

This document defines terms in the field of the sterilization of health care products including related equipment and processes.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
A_0
measure of microbiological lethality delivered by a moist heat disinfection process expressed in terms of the equivalent time in seconds at 80 °C with reference to a microorganism with a *z* value of 10 K

3.2
absolute pressure
pressure for which the zero value is associated with absolute vacuum

3.3
absorbed dose
<radiation> quantity of ionizing radiation energy imparted per unit mass of a specified material

3.4
access device
means by which entry to restricted parts of equipment is achieved

Note 1 to entry: This can be by dedicated key, code, or tool.

3.5
action level
value from monitoring that necessitates immediate intervention

3.6
active ingredient
chemical or biological component that is included in the formulation of a health care product to achieve the intended purpose

3.7
aeration
part of the sterilization cycle during which the sterilizing agent and/or its reaction products desorb from the health care product until predetermined levels are reached

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