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

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 15882:2003 sisaldab Euroopa standardi EN ISO 15882:2003 ingliskeelset teksti. Käesolev dokument on jõustatud 14.08.2003 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 15882:2003 consists of the English text of the European standard EN ISO 15882:2003. This document is endorsed on 14.08.2003 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala:	**Scope:**

ICS 11.080

Võtmesõnad:

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 15882

March 2003

ICS 11.080.01

English version

Sterilization of health care products – Chemical indicators

Guidance for selection, use and interpretation of results
(ISO 15882 : 2003)

Stérilisation des produits de santé – Indicateurs chimiques – Lignes directrices pour le choix, l'emploi et l'interprétation des résultats
(ISO 15882 : 2003)

Sterilisation von Produkten für die Gesundheitsfürsorge – Chemische Indikatoren – Leitfaden für die Auswahl, Verwendung und Interpretation von Ergebnissen (ISO 15882 : 2003)

This European Standard was approved by CEN on 2003-03-11.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, the Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Management Centre: rue de Stassart 36, B-1050 Brussels

Ref. No. EN ISO 15882 : 2003 E

Foreword

International Standard

ISO 15882 : 2003 Sterilization of health care products – Chemical indicators – Guidance for selection, use and interpretation of results,

which was prepared by ISO/TC 198 'Sterilization of health care products' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 102 'Sterilizers for medical purposes', the Secretariat of which is held by DIN, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by September 2003 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, the Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 15882 : 2003 was approved by CEN as a European Standard without any modification.

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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.

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)