Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 11137-3:2006 sisaldab Euroopa standardi EN ISO 11137-3:2006 ingliskeelset teksti. Käesolev dokument on jõustatud 29.05.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 11137-3:2006 consists of the English text of the European standard EN ISO 11137-3:2006. This document is endorsed on 29.05.2006 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This part of ISO 11137 gives guidance on the requirements in ISO 11137 parts 1 and 2 relating to dosimetry. Dosimetry procedures related to the development, validation and routine control of a radiation sterilization process are described.	**Scope:** This part of ISO 11137 gives guidance on the requirements in ISO 11137 parts 1 and 2 relating to dosimetry. Dosimetry procedures related to the development, validation and routine control of a radiation sterilization process are described.

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Võtmesõnad:

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EN ISO 11137-3

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Supersedes EN 552:1994

English Version

Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects (ISO 11137-3:2006)

Stérilisation des produits de santé - Irradiation - Partie 3: Directives relatives aux aspects dosimétriques (ISO 11137-3:2006)

Sterilisation von Produkten für die Gesundheitsfürsorge - Strahlen - Teil 3: Anleitung zu dosimetrischen Aspekten (ISO/FDIS 11137-3:2006)

This European Standard was approved by CEN on 13 April 2006.

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 Central Secretariat or to any CEN member.

This European Standard exists 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 Central Secretariat has the same status as the official versions.

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

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 11137-3:2006: E

Foreword

This document (EN ISO 11137-3:2006) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 204 "Sterilization of medical devices", the secretariat of which is held by BSI.

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 October 2006, and conflicting national standards shall be withdrawn at the latest by April 2009.

This document supersedes EN 552:1994.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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

Endorsement notice

The text of ISO 11137-3:2006 has been approved by CEN as EN ISO 11137-3:2006 without any modifications.

ANNEX ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directives 90/385/EEC concerning active implantable medical devices, 93/42/EEC concerning medical devices and 98/79/EEC concerning *in vitro* diagnostic medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive, EU Directives 90/385/EEC concerning active implantable medical devices, 93/42/EEC concerning medical devices and 98/79/EEC concerning *in vitro* diagnostic medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and EU Directives 90/385/EEC concerning active implantable medical devices, 93/42/EEC concerning medical devices and 98/79/EEC concerning *in vitro* diagnostic medical devices

Clause(s)/Sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 90/385/EEC	Essential Requirements (ERs) of Directive 93/42/EEC	Essential Requirements (ERs) of Directive 98/79/EEC	Qualifying remarks/Notes
4, 5, 6, 7, 8, 9, 10, 11, 12	7	8.3	B.2.3	In part
4, 5, 6, 7, 8, 9, 10, 11, 12		8.4	B.2.4	In part

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 11137-3

First edition
2006-04-15

Sterilization of health care products — Radiation —

Part 3: Guidance on dosimetric aspects

Stérilisation des produits de santé — Irradiation —

Partie 3: Directives relatives aux aspects dosimétriques

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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 11137-3 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care product*.

This first edition, together with ISO 11137-1 and ISO 11137-2, cancels and replaces ISO 11137:1995.

ISO 11137 consists of the following parts, under the general title *Sterilization of health care products — Radiation*:

— *Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

— *Part 2: Establishing the sterilization dose*

— *Part 3: Guidance on dosimetric aspects*

Introduction

An integral part of radiation sterilization is the ability to measure dose. Dose is measured during all stages of development, validation and routine monitoring of the sterilization process. It has to be demonstrated that dose measurement is traceable to a national or International Standard, that the uncertainty of measurement is known, and that the influence of temperature, humidity and other environmental considerations on dosimeter response is known and taken into account. Process parameters are established and applied based on dose measurements. This part of ISO 11137 provides guidance on the application of dose measurements (dosimetry) during all stages of the sterilization process.

ISO 11137-1 describes requirements that, if met, will provide a radiation sterilization process, intended to sterilize medical devices, which has appropriate microbicidal activity. Furthermore, compliance with the requirements helps ensure that this activity is both reliable and reproducible so that predictions can be made, with reasonable confidence, that there is a low level of probability of there being a viable microorganism present on product after sterilization.

Generic requirements of the quality management system for design and development, production, installation and servicing are given in ISO 9001 and particular requirements for quality management systems for medical device production are given in ISO 13485. The standards for quality management systems recognize that, for certain processes used in manufacturing or reprocessing, the effectiveness of the process cannot be fully verified by subsequent inspection and testing of the product. Sterilization is an example of such a process. For this reason, sterilization processes are validated for use, the performance of the sterilization process monitored routinely and the equipment maintained.

Requirements in regard to dosimetry are given in ISO 11137-1 and ISO 11137-2. This part of ISO 11137 gives guidance to these requirements. The guidance given is not normative and is not provided as a checklist for auditors. The guidance provides explanations and methods that are regarded as being suitable means for complying with the requirements. Methods other than those given in the guidance may be used, if they are effective in achieving compliance with the requirements of ISO 11137-1.

Sterilization of health care products — Radiation —

Part 3: Guidance on dosimetric aspects

1 Scope

This part of ISO 11137 gives guidance on the requirements in ISO 11137 parts 1 and 2 relating to dosimetry. Dosimetry procedures related to the development, validation and routine control of a radiation sterilization process are described.

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

ISO 11137-2:2006, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11137-1, ISO 11137-2 and the following apply.

3.1
dosimetry system
interrelated elements used for determining absorbed dose, including dosimeters, instruments, associated reference standards and procedures for their use

[ISO/TS 11139:2005]

4 Measurement of dose

Measurement of absorbed dose in connection with the radiation sterilization of medical devices is expressed in terms of absorbed dose to water. Dosimetry systems should be calibrated in terms of absorbed dose to water. In this part of ISO 11137, absorbed dose is referred to as dose.