EESTI STANDARD EVS-EN ISO 17664:2004

Meditsiiniseadmete steriliseerimine. Tootja poolt esitatav informatsioon resteriliseeritavate meditsiiniseadmete käitlemise kohta

Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 17664:2004 sisaldab Euroopa standardi EN ISO 17664:2004 ingliskeelset teksti. Käesolev dokument on jõustatud 18.06.2004 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 17664:2004 consists of the English text of the European standard EN ISO 17664:2004. This document is endorsed on 18.06.2004 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 standard specifies the information to be provided by the medical device manufacturer on the processing of medical devices claimed to be re-sterilizable and medical devices intended to be sterilized by the processor.	**Scope:** This standard specifies the information to be provided by the medical device manufacturer on the processing of medical devices claimed to be re-sterilizable and medical devices intended to be sterilized by the processor.

ICS 11.080.01

Võtmesõnad:

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 17664

March 2004

ICS 11.080.01

English version

Sterilization of medical devices

Information to be provided by the manufacturer for the processing of resterilizable medical devices

(ISO 17664 : 2004)

Stérilisation des dispositifs médicaux – Informations devant être fournies par le fabricant pour le processus de restérilisation des dispositifs médicaux (ISO 17664 : 2004)

Sterilisation von Medizinprodukten – Vom Hersteller bereitzustellende Informationen für die Aufbereitung von resterilisierbaren Medizinprodukten (ISO 17664 : 2004)

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

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, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, 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 17664 : 2004 E

Contents

Foreword

This document (EN ISO 17644:2004) has been prepared by Technical Committee CEN/TC 204 "Sterilization of medical devices", the secretariat of which is held by BSI, in collaboration with Technical Committee ISO/TC 198 "Sterilization of health care products".

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 September 2004, and conflicting national standards shall be withdrawn at the latest by September 2004.

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).

Informative annexes A and B are attached to 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This standard applies to those medical devices which are intended for multiple use and require processing to take them from their state at the end of one use to the state of being sterile and ready for their subsequent use. Some medical devices supplied non-sterile but intended to be used in a sterile state, will also require similar treatment.

1 Scope

This standard specifies the information to be provided by the medical device manufacturer on the processing of medical devices claimed to be re-sterilizable and medical devices intended to be sterilized by the processor.

This standard specifies requirements for the information to be provided by the medical device manufacturer, so that the medical device can be processed safely and will continue to meet its performance specification.

Requirements are specified for processing that consists of all or some of the following activities:

— preparation at the point of use;

— preparation, cleaning, disinfection;

— drying;

— inspection, maintenance and testing;

— packaging;

— sterilization;

— storage.

When providing instructions for these activities, medical device manufacturers are expected to be aware of the training and knowledge of procedures, and of the processing equipment available to the persons likely to be responsible for processing. It is likely that some processing procedures will be generic and well known and will use equipment and consumables conforming to recognized standards. In this case, a reference in the instructions is all that is required. For those medical devices where instructions for use are not required to accompany the medical device, other means of communicating the information can be used, e.g. user manuals, symbols or wall charts supplied separately.

This standard excludes textile devices used in patient draping systems or surgical clothing.

NOTE The principles of this standard may be applied when considering the information to be supplied with medical devices which only require disinfection prior to re-use.

2 Terms and definitions

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

2.1
chemical
formulation of compounds intended for use in reprocessing

NOTE This includes, for example, detergents, surfactants, rinse aids, disinfectants, enzymatic cleaners, sterilants.

2.2
cleaning
removal of contamination from an item to the extent necessary for further processing or for intended use