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Biologisk värdering av medicintekniska produkter – Del 17: Förfarande att fastställa tillåtliga gränsvärden för utlösliga ämnen (ISO 10993-17:2002)

Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)

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Europastandarden EN ISO 10993-17:2009 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 10993-17:2009.

Denna standard ersätter SS-EN ISO 10993-17, utgåva 1.

The European Standard EN ISO 10993-17:2009 has the status of a Swedish Standard. This document contains the official English version of EN ISO 10993-17:2009.

This standard supersedes the Swedish Standard SS-EN ISO 10993-17, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00.
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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Supersedes EN ISO 10993-17:2002

English Version

Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)

Évaluation biologique des dispositifs médicaux - Partie 17: Établissement des limites admissibles des substances relargables (ISO 10993-17:2002)

Biologische Beurteilung von Medizinprodukten - Teil 17: Nachweis zulässiger Grenzwerte für herauslösbare Bestandteile (ISO 10993-17:2002)

This European Standard was approved by CEN on 12 April 2009.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

The text of ISO 10993-17:2002 has been prepared by Technical Committee ISO/TC 194 “Biological evaluation of medical devices” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 10993-17:2009 by Technical Committee CEN/TC 206 “Biological evaluation of medical devices” the secretariat of which is held by NEN.

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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document supersedes EN ISO 10993-17:2002.

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 Directives 93/42/EEC on Medical Devices and 90/385/EEC on Active Implantable Medical Devices.

For relationship with the EU Directives, see informative Annexes ZA and ZB, 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, Bulgaria, 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 the United Kingdom.

Endorsement notice

The text of ISO 10993-17:2002 has been approved by CEN as a EN ISO 10993-17:2009 without any modification.

Introduction

The determination of the suitability of a medical device for a particular use involves balancing any identified risks with the clinical benefit to the patient associated with its use. Among the risks to be considered are those arising from exposure to leachable substances arising from medical devices.

Risks associated with exposure to hazardous leachable substances are managed by identifying the leachable substances, quantifying the associated risks and limiting exposure within tolerable levels. This part of ISO 10993 provides a method by which maximum tolerable levels can be calculated from available data on health risks. Allowable limits may be based upon health risks that can be systemic or local, immediate or delayed, and range in severity from minor localized adverse effects to life-threatening risks. These allowable limits are intended to be derived, using this part of ISO 10993, by toxicologists or other knowledgeable and experienced individuals, capable of making informed decisions based upon scientific data and a knowledge of medical devices.

The allowable limits derived may be used by anyone. In addition to use by ISO, other standards-developing organizations, government agencies, regulatory bodies, and other users for setting allowable limits as standards or regulations, manufacturers and processors may use the allowable limits derived to optimize processes and aid in the choice of materials in order to protect patient health. Where risks associated with exposure to particular leachable substances are unacceptable, this part of ISO 10993 can be used to qualify alternative materials or processes.

Biological evaluation of medical devices —

Part 17:
Establishment of allowable limits for leachable substances

1 Scope

This part of ISO 10993 specifies a method for the determination of allowable limits for substances leachable from medical devices. It is intended for use in deriving standards and estimating appropriate limits where standards do not exist. It describes a systematic process through which identified risks arising from toxicologically hazardous substances present in medical devices can be quantified.

This part of ISO 10993 is not applicable to devices that have no patient contact (e.g. *in vitro* diagnostic devices).

Exposure to a particular chemical substance may arise from sources other than the device, such as food, water or air. This part of ISO 10993 does not address the potential for exposure from such sources.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this part of ISO 10993. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 10993 are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

3 Terms and definitions

For the purposes of this part of ISO 10993, the terms and definitions given in ISO 10993-1 and the following apply.

3.1
allowable limit
AL
largest amount of a leachable substance that is deemed acceptable on a daily basis, when taken into the body through exposure to a medical device

NOTE Allowable limits are expressed in dose to the patient for each applicable exposure period. The units used are mass per unit time, e.g. milligrams per day. These doses represent tolerable risks for medical devices under the circumstances of intended use.

3.2
benefit factor
BF
numerical factor that takes into account the health benefit from use of the medical device(s) containing the leachable substance in question

3.3
concomitant exposure factor
CEF
numerical factor that accounts for patient exposure to many medical devices containing the same leachable substance

NOTE This factor is used to adjust the product of TI and body mass downward.

3.4
default
value to be used, in the absence of data, for an uncertainty or other factor used in the calculation of the allowable limit

3.5
harm to health
physical injury and/or damage to health

3.6
health benefit
likelihood of maintaining or improving health

3.7
health hazard
potential source of harm to health

3.8
health risk
combination of the likelihood of occurrence of harm to health and the severity of that harm

3.9
health risk analysis
use of available information to identify health hazards and to estimate health risk

3.10
leachable substance
chemical removed from a medical device by the action of water or other liquids related to the use of the device

EXAMPLE Additives, sterilant residues, process residues, degradation products, solvents, plasticizers, lubricants, catalysts, stabilizers, anti-oxidants, colouring agents, fillers and monomers, among others.

3.11
lowest observed adverse effect level
LOAEL
lowest concentration or amount of a substance found by experiment or observation which causes detectable adverse alteration of morphology, functional capacity, growth, development or life span of the target organism under defined conditions of exposure

NOTE Alterations in morphology, functional capacity, growth, development or life span of the target organism may be detected which are judged not to be adverse.

3.12
minimally irritating level
MIL
amount of a leachable substance that is minimally irritating to the patient

NOTE It is normally expressed in milligrams, although sometimes as milligrams per millilitre, in which case the value must be multiplied by the volume (millilitres) used to get the mass (milligrams).

3.13
modifying factor
MF
mathematical product of uncertainty factors UF_1, UF_2 and UF_3

3.14
multiple exposure
more than one exposure of the same patient to devices containing the same leachable substance, simultaneously or at different times

3.15
non-irritating level
NIL
largest amount of a leachable substance that is not irritating to the patient

NOTE It is normally expressed in milligrams, although sometimes as milligrams per millilitre, in which case the value must be multiplied by the volume (millilitres) used to get the mass (milligrams).

3.16
no observed adverse effect level
NOAEL
greatest concentration or amount of a substance found by experiment or observation which causes no detectable adverse alteration of morphology, functional capacity, growth, development or life span of the target organism under defined conditions of exposure

NOTE Alterations of morphology, functional capacity, growth, development or life span of the target organism may be detected which are judged not to be adverse.

3.17
physiologically based pharmacokinetic modelling
PBPK modelling
system of modelling biological effects taking into account metabolic and pharmacokinetic differences among species of animal

NOTE Such data should be utilized whenever they are available.

3.18
proportional exposure factor
PEF
numerical factor for patient exposure to a leachable substance that accounts for the fact that a medical device is not typically utilized every day during the entire exposure category of interest

NOTE This factor is used to adjust the product of TI and body mass upwards.

3.19
repeated use
use of the same device by the same patient more than once without reprocessing

3.20
safety
freedom from unacceptable health risk

3.21
simultaneous use
use of more than one device by the same patient at the same time