Inimeste tarbeks ettenähtud meditsiiniseadmete kliiniline uurimine

Clinical investigation of medical devices for human subject

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 540:1999 sisaldab Euroopa standardi EN 540:1993 ingliskeelset teksti.	This Estonian standard EVS-EN 540:1999 consists of the English text of the European standard EN 540:1993.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 28.06.1993.	Date of Availability of the European standard is 28.06.1993.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.020

Võtmesõnad: accident prevention, clinical testing, commerce, estimation, hazards, humans, medical equipment, safety, specifications,

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 540:1993

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Descriptors: Medical equipment, safety, accident prevention, hazards, estimation, humans, clinical testing, specifications, commerce

English version

Clinical investigation of medical devices for human subjects

Investigation clinique des dispositifs médicaux sur les sujets humains

Klinische Prüfung von medizinischen Geräten für Versuchspersonen

This European Standard was approved by CEN on 1993-06-21. 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.

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 Central Secretariat has the same status as the official versions.

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

CEN

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

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Contents list

Foreword

This European Standard was prepared by CEN TC 258 "CLINICAL INVESTIGATION of MEDICAL DEVICES".

This European Standard has been prepared under a Mandate given to CEN by the Commission of the European Communities (and the secretariat of the European Free Trade Association) and supports Annexes on Clinical Evaluation of relevant EC Directive(s).

In this European Standard, the words defined in clause 3 are written in capital letters.

International work is currently underway within ISO TC 194/WG 4, and this European Standard is in technical conformity with ISO CD 10993-8 which deals with the same subject.

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 December 1993, and conflicting national standards shall be withdrawn at the latest by December 1993.

According to the CEN/CENELEC Internal Regulations, the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

0 Introduction

This European Standard was prepared to define procedures to assist manufacturers, regulatory authorities,SPONSORS and CLINICAL INVESTIGATORS on the conduct and performance of the CLINICAL INVESTIGATION of MEDICAL DEVICES.

This European Standard is intended to protect SUBJECTS and ensure the scientific conduct of the CLINICAL INVESTIGATION.

Clinical investigation of medical devices for human subjects

1 Scope

1.1 This European Standard pertains to the CLINICAL INVESTIGATION in human SUBJECTS of those MEDICAL DEVICES whose the clinical PERFORMANCE needs assessment before being placed on the market.

This European standard does not apply to in vitro diagnostic devices.

1.2 This European Standard specifies the requirements :

- for the conduct of CLINICAL INVESTIGATIONS and documentation on whether the MEDICAL DEVICE achieves the performance intended by the SPONSOR,

- to determine any undesirable side effects, under normal conditions of use,

- to permit the assessment of the acceptable risks having regard to the intended PERFORMANCE OF THE MEDICAL DEVICE.

1.3 This European Standard provides a framework for the preparation of written procedures for the organisation, design, implementation, data collection and documentation of the CLINICAL INVESTIGATION.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

World Medical Association Declaration of Helsinki ; recommendations guiding physicians in biomedical research involving human subjects.

3 Terminology and definitions

For the purpose of this European Standard, the following definitions apply:

3.1 medical device : any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended