Meditsiiniseadmed. Riskianalüüs

Medical devices - Risk analysis

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 1441:2000 sisaldab Euroopa standardi EN 1441:1997 ingliskeelset teksti.	This Estonian standard EVS-EN 1441:2000 consists of the English text of the European standard EN 1441:1997.
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 22.10.1997.	Date of Availability of the European standard is 22.10.1997.
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 11.040.01

Võtmesõnad: acceptability, accident prevention, estimation, hazards, information, medical equipment, safety, specifications, statistical analysis,

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN 1441

October 1997

ICS 11.040.01

Descriptors: medical equipment, safety, accident prevention, hazards, statistical analysis, estimation, acceptability, specifications, information

English version

Medical devices - Risk analysis

Dispositifs médicaux - Analyse des risques

Medizinprodukte - Risikoanalyse

This European Standard was approved by CEN on 13 September 1997.

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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

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Foreword

This European Standard has been prepared by BTS 3 /WG 1 "Risk assessment of medical devices" of CEN/CS.

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 April 1998, and conflicting national standards shall be withdrawn at the latest by April 1998.

This European Standard 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.

For relationship with EU Directives, see informative annex ZA which is an integral part of this standard.

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, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Annexes A, B, C, D and E are informative.

Introduction

Judgements relating to safety, including the acceptability of risks, are necessary in order to determine the suitability for use of a medical device. Factors influencing the perception of safety include the socio-economic and educational background of the society concerned and the actual and projected situation and status of the patient. Such judgements take into account the intended use, performance, risks and benefits of the device and the risks and benefits associated with the clinical procedure.

The overall process for the control of risk is referred to as risk management. During the design phase of a medical device a manufacturer will need to analyse the hazards and risks associated with the use of a device. This standard addresses that phase of the risk management process.

Relevant standards mentioned within this standard include harmonized European standards, the references of which has been published in the Official Journal of the European Communities.

1 Scope

This standard specifies a procedure for the manufacturer to investigate, using available information, the safety of a medical device, including in vitro diagnostic devices or accessories, by identifying hazards and estimating the risks associated with the device. It is of particular assistance in areas where relevant standards are not available or not used.

This standard does not stipulate levels of acceptability, which because they are determined by a multiplicity of factors, cannot by their nature be set down in such a standard.

This standard is not intended to give detailed guidance on management of risks. Furthermore, it is not intended to cover decision-making processes regarding assessment of the indications and contra-indications for the use of a particular device.

2 Definitions

For the purposes of this standard, the following definitions apply:

2.1 harm: Physical injury and/or damage to health or property. [ISO/IEC Guide 51:1990]

2.2 hazard: A potential source of harm. [ISO/IEC Guide 51:1990]

2.3 risk: The probable rate of occurrence of a hazard causing harm and the degree of severity of the harm. [ISO/IEC Guide 51:1990]

2.4 risk analysis: The investigation of available information to identify hazards and to estimate risks.

2.5 safety: Freedom from unacceptable risk of harm. [ISO/IEC Guide 51:1990]