EESTI STANDARD EVS-ENV 13004:2000

Nomenclature system for medical devices for the purposes of regulatory data exchange - Recommendations for an interim system and rules for a future system

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-ENV 13004:2000 sisaldab Euroopa standardi ENV 13004:1999 ingliskeelset teksti.	This Estonian standard EVS-ENV 13004:2000 consists of the English text of the European standard ENV 13004:1999.
Standard on kinnitatud Eesti Standardikeskuse 11.01.2000 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 11.01.2000 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 01.040.11, 01.040.35, 35.240.70

EUROPEAN PRESTANDARD
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English version

Nomenclature system for medical devices for the purposes of regulatory data exchange - Recommendations for an interim system and rules for a future system

Système de nomenclature des dispositifs médicaux aux fins d'échanges de données réglementaires - Recommandations relatives à un système intérimaire et règles applicables à un futur système

Nomenklatursysteme für Medizinprodukte zum Zwecke des regulativen Datenaustauschs - Empfehlungen für ein Übergangssystem und Regeln für ein zukünftiges System

This European Prestandard (ENV) was approved by CEN on 6 May 1999 as a prospective standard for provisional application.

The period of validity of this ENV is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the ENV can be converted into a European Standard.

CEN members are required to announce the existence of this ENV in the same way as for an EN and to make the ENV available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV into an EN is reached.

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

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Foreword

This European Prestandard has been prepared by Technical Committee CEN/TC 257 "Symbols and information provided with medical devices and nomenclature for regulatory data exchange", the secretariat of which is held by SFS.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European prestandard has been prepared at the request of the European Commission and the European Free Trade Association as an interim measure to give guidance to Competent Authorities, Notified bodies and manufacturers of medical devices while CEN/TC 257/SC1 developes a detailed nomenclature system for regulatory data exchange.

This European prestandard will be withdrawn on publication of EN 1874 "Nomenclature - Specification for a nomenclature system for the purpose of regulatory data exchange".

1 Scope

This European prestandard gives guidance for the nomenclature of medical devices for regulatory data exchange. It is intended for use by Competent Authorities, Notified Bodies and manufacturers of medical devices.

NOTE 1. The competent authority is the body which has the authority to act on behalf of the government of a Member State to ensure that the requirements of the medical devices Directive are carried out in that particular member state.

NOTE 2. The notified body, as defined in the European Commission Guide to the implementation of Community harmonization directives based on the new approach and the global approach, is a third party authorized to perform the conformity assessment tasks specified in the directive, which has been appointed by a member state from the bodies falling within its jurisdiction, which has the necessary qualifications, meets the requirements laid down in the directive and has been notified to the Commission and other Member States.

2 Definition

2.1 nomenclature: system of terms which is elaborated according to pre-established naming rules.

3 Recommendations

3.1 Interim measures

The ECRI Product Categories Thesaurus [1)] should be used for the purposes of regulatory data exchange.

If the ECRI system does not cover a particular area the nomenclature should be based on established European and International Standards for classification or similar documents prepared by European or International trade associations.

NOTE. Annex A contains a bibliography of suitable reference documents.

[1)] The ECRI Product Categories Thesaurus can be obtained from ECRI - 5200 Butler Pike, Plymouth Meeting, PA 19462-1298 USA.