SLOVENSKI STANDARD
SIST ENV 13004:2000

01-julij-2000

Sistem poimenovanja medicinskih pripomočkov za obvezno izmenjavo podatkov - Priporočila za začasni sistem in pravila za prihodnji sistem

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

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

Systeme de nomenclature des dispositifs médicaux aux fins d'échanges de données réglementaires - Recommandations relatives a un systeme intérimaire et regles applicables a un futur systeme

Ta slovenski standard je istoveten z: **ENV 13004:1999**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

SIST ENV 13004:2000 **en**

EUROPEAN PRESTANDARD

PRÉNORME EUROPÉENNE

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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

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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.

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

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Contents

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.

3.2 Rules for future system

The nomenclature should be a three level hierarchical system as follows:

a) device category;

b) generic device group; and

c) device type

NOTE: Annex B shows the general structure of the proposed future system.

Annex A (informative)

Bibliography

EN 60601-1 : 1988	Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1)
ISO 704	Principles and methods of terminology
ISO 1087	Terminology - Vocabulary
EN ISO 4135	Anaesthesiology - Vocabulary (ISO 4135 : 1995)
EN 29999	Technical aids for disabled persons - Classification (ISO 9999 : 1992)
COCIR- EUROM	Classification catalogue for medical devices
EDMA	Product classifications for in vitro diagnostic products
FDA SPN	Standards product nomenclature
JFMDA	Medical device nomenclature