SLOVENSKI STANDARD
SIST EN ISO 15225:2000/A2:2005

01-september-2005

Poimenovanje – Specifikacija za sistem poimenovanja medicinskih pripomočkov za obvezno izmenjavo podatkov (ISO 15225:2000/Amd 1:2004)

Nomenclature - Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange (ISO 15225:2000/Amd 1:2004)

Nomenklatur - Spezifikation für ein Nomenklatursystem für Medizinprodukte zum Zweck des regulativen Datenaustauschs (ISO 15225:2000/Amd 1:2004)

Nomenclature - Spécifications pour un système de nomenclature des dispositifs médicaux destiné a l'échange de données réglementaires (ISO 15225:2000/Amd 1:2004)

Ta slovenski standard je istoveten z: **EN ISO 15225:2000/A2:2005**

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 EN ISO 15225:2000/A2:2005 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15225:2000/A2

July 2005

ICS 11.040.01; 35.240.80

English version

Nomenclature - Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange (ISO 15225:2000/Amd 1:2004)

Nomenclature - Spécifications pour un système de nomenclature des dispositifs médicaux destiné à l'échange de données réglementaires (ISO 15225:2000/Amd 1:2004)

Nomenklatur - Spezifikation für ein Nomenklatursystem für Medizinprodukte zum Zweck des regulativen Datenaustauschs (ISO 15225:2000/Amd 1:2004)

This amendment A2 modifies the European Standard EN ISO 15225:2000; it was approved by CEN on 27 June 2005.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

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Ref. No. EN ISO 15225:2000/A2:2005: E

Foreword

This document (EN 15225:2000/A2:2005) 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.

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 January 2006, and conflicting national standards shall be withdrawn at the latest by January 2006.

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 Directive(s).

For relationship with EU Directive(s), see informative Annex ZC, 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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 15225:2000/Amd 1:2004 has been approved by CEN as EN ISO 15225:2000/A2:2005 without any modifications.

Contents

At the end of the existing table of contents in EN ISO 15225:2000, insert the following new entry:

Annex ZC (informative) Relationship between this European Standard and the Essential Requirements of Directive 98/79/EC

Add the following Annex ZC.

Annex ZC
(informative)

Relationship between this European Standard and the Essential Requirements of Directive 98/79/EC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 98/79/EC.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZC.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Table ZC.1 - Correspondence between this European Standard and Directive 98/79/EC

Clause(s)/Sub-clause(s) of this European Standard	Essential requirements (ERs) from Council Directive on in vitro diagnostic medical devices (98/79/EC)	Qualifying Remarks /Notes
6.2, 6.3, 6.4, 6.5	Article 4, Clause 4	
This standard	Article 8, Clause 3	
This standard	Article 9, Clause 4	
This standard	Article 10, Clauses 1, 2, 4, 5, 6	
This standard	Article 11, Clauses 1, 2, 3	
This standard	Article 12, Clauses 1,2, 3	
This standard	Article 14, Clauses 1, 2, 3	
This standard	Article 15, Clauses 5, 6	
This standard	Annex I, Clause B.8.4 b)	
This standard	Annex I, Clause B.8.7 a)	
This standard	Annex I, Clause B.8.7.m	
This standard, 5.3, 6	Annex III. Clause 3	
This standard, 5, 6	Annex IV, Clause 3.1	
This standard, 5, 6	Annex V, Clauses 3, 5	
This standard, 5.3, 6	Annex VII, Clause 3.1	
This standard, 5, 6	Annex VIII, Clause 2	

INTERNATIONAL STANDARD

ISO 15225

First edition
2000-09-15

AMENDMENT 1
2004-02-01

Nomenclature — Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange

AMENDMENT 1

Nomenclature — Spécifications pour un système de nomenclature des dispositifs médicaux destiné à l'échange de données réglementaires

AMENDEMENT 1

Reference number
ISO 15225:2000/Amd.1:2004(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

Amendment 1 to ISO 15225:2000 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.