

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

The European Standard EN ISO 15225:2000, with the incorporation of amendments A1:2004 and A2:2005, has the status of a British Standard

ICS 01.040.11; 01.040.35; 11.040.01; 35.240.80

National foreword

This British Standard is the official English language version of EN ISO 15225:2000, including amendments A1:2004 and A2:2005. It is identical with ISO 15225:1999, including amendment 1:2004.

The start and finish of text introduced or altered by ISO amendment is indicated in the text by tags **A1** **A1**. Tags indicating changes to ISO text carry the number of the amendment. For example, text altered by ISO amendment 1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted by Technical Committee CH/68, General terminology, symbols and information provided with medical devices, to Subcommittee CH/68/2, Identification, coding, nomenclature and regulatory data sets for medical devices, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled “International Standards Correspondence Index”, or by using the “Search” facility of the *BSI Electronic Catalogue* or of British Standards Online.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 April 2000

Summary of pages

This document comprises a front cover, an inside front cover, the EN ISO title page, pages 2 to 27 and a back cover.

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Amendments issued since publication

Amd. No.	Date	Comments
15036	31 March 2004	See national foreword
15844	9 November 2005	See national foreword

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ISBN 0 580 35786 4

ICS 01.040.11; 11.040.01; 11.120.01

English version

**Nomenclature - Specification for a nomenclature system for
medical devices for the purpose of regulatory data exchange**
(including amendments A1:2004 and A2:2005)
(ISO 15225:2000 + A1:2004)

Nomenclature - Spécifications pour un système de
nomenclature des dispositifs médicaux destiné à l'échange de
données réglementaires
(inclut les amendements A1:2004 et A2:2005)
(ISO 15225:2000 + A1:2004)

Nomenklatur - Spezifikation für ein Nomenklatursystem für
Medizinprodukte zum Zweck des regulativen Datenaustauschs
(enthält Änderungen A1:2004 und A2:2005)
(ISO 15225:2000 + A1:2004)

This European Standard was approved by CEN on 15 November 1999; amendment A1 was approved by CEN on 2 February 2004 and amendment A2:2005 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 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 Management Centre or to any CEN member.

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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.



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Foreword

The text of EN ISO 15225:2000 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, in collaboration with Technical Committee ISO/TC 210 “Quality management and corresponding general aspects for medical devices”.

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 August 2000, and conflicting national standards shall be withdrawn at the latest by August 2000.

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 Directive(s).

This standard has been prepared by CEN/TC 257. It is the endorsement of ISO 15225 with the necessary common modifications. It is intended to complement the specific requirements of the EU Directives on medical devices relating to the information exchanged between parties communicating in conformity with requirements of the Directives.

For relationship with EU Directive(s), see informative Annexes ZA and ZB, which are integral parts 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.

Foreword to amendment A1

This document (EN ISO 15225:2000/A1:2004) has been prepared by Technical Committee ISO/TC 210 “Quality management and corresponding general aspects for medical devices” in collaboration with 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.

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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 ZA, which is an integral part of this document.

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NOTE FROM CMC The foreword is susceptible to be amended on reception of the German language version. The confirmed or amended foreword, and when appropriate, the normative annex ZA for the references to international publications with relevant European publications will be circulated with the German version.

Endorsement notice

The text of ISO 15225:2000 has been approved by CEN as EN ISO 15225:2000/A1:2004 without any modifications.

Foreword to amendment A2

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.

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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.

Introduction

This European Standard gives rules and guidelines for the construction of a nomenclature system for medical devices in order to enable Competent Authorities, Notified Bodies and manufacturers to meet the requirements of Council Directives on medical devices. It is also intended to assist in the implementation of community sectoral legislation and to facilitate co-operation and exchange of information within the European Community and at international level. It is intended that this assistance and facilitation could be extended to other relevant parties such as Regulatory Bodies and Health Care Providers.

This European Standard also gives the requirements for a minimum data set and relating to this data system its structure. These requirements are provided for system designers setting up databases utilizing the nomenclature system described herein. It is intended that the information covered by this standard should be available in the public domain.

The requirements contained in this standard are applicable to the development and updating of a European Nomenclature for medical devices.

This European Standard provides rules and guidelines for nomenclature design, which will ensure that nomenclatures built upon this standard will be simple to use, rational, applicable by all grades and professions of users and suitable for both computerized systems and printed matter.

In order to avoid the proliferation of nomenclature systems, even though each may be in conformity with this standard, it is desirable that a control body be set up to administer and maintain the European Nomenclature system. This standard has been prepared with the needs of such a body in mind and to provide ease of management at reasonable cost.

It is anticipated that the European Gatekeeper will liaise with other bodies responsible for maintaining nomenclatures in other regulatory environments, with a view to appropriate international harmonization.

1 Scope

This European Standard specifies requirements and guidance for the construction of a nomenclature for medical devices in order to facilitate co-operation and exchange of regulatory data on an international level between interested parties such as: Regulatory Authorities, Manufacturers, Suppliers, Health Care Providers, and End Users.

NOTE 1: This European Standard includes guidelines for a minimum data set and its structure. These guidelines are provided for system designers setting up databases utilizing the nomenclature system described herein.

The requirements contained in this standard are applicable to the development and maintenance of a European nomenclature for medical device identification.

NOTE 2: This European Standard will not include the nomenclature itself. The nomenclature will be supplied as a separate document.

NOTE 3: It is intended to complement the specific requirements of the EC Directives on medical devices in the context of specifying means by which common identification can be achieved between bodies required to exchange data in conformity with the requirements of the Directives.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 1087 : 1990	Terminology - Vocabulary
ISO/IEC 8859-1 : 1998	Information processing - 8-bit single-byte coded graphic character sets
ISO/IEC 2382-1 : 1993	Information technology - Vocabulary - Part 1: Fundamental terms
ISO 2382-4 : 1987	Information processing systems - Vocabulary - Part 4: Organization of data
ISO/IEC 2382-17 : 1996	Information technology - Vocabulary - Part 17: Databases

NOTE: Other documents which may be useful for the understanding of this standard are listed in the Bibliography.

3 Definitions

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

NOTE: Many terms are used in this document which have their basis in regulatory statutes. Examples of these words are “medical device”, “custom made medical device” and “manufacturer”. These terms are defined in the respective jurisdictions where the nomenclature will be used. There is no attempt to define these terms in this document because of potential conflicts with the legal definitions of the respective jurisdiction. This standard has been crafted so as to transcend and avoid substantive conflict of different definitions of these terms.

3.1 character: A member of a set of elements used for the organization, control or representation of data [ISO/IEC 8859-1:1998].

3.2 concept: A unit of thought constituted through abstraction on the basis of properties common to a set of objects [ISO 1087:1990].

3.3 device category: No definition available.

NOTE: 4.2 contains a description of the term “device category”.

3.4 device type: No definition available.

NOTE: 4.4 contains a description of the term ‘device type’.

3.5 file: A named set of records stored or processed as a unit [ISO/IEC 2382-1:1993].

3.6 foreign key: In a relation, one or a group of attributes that corresponds to a primary key in another relation [ISO/IEC 2382-17:1996].

3.7 generic device group: No definition available.

NOTE: 4.3 contains a description of the term ‘generic device group’

3.8 identifier: One or more characters used to identify or name a data element and possibly to indicate certain properties of that data element [ISO 2382-4:1987].

3.9 name: Designation of an object by an linguistic expression [ISO 1087:1990].

3.10 nomenclature: System of terms which is elaborated according to pre-established naming rules [ISO 1087:1990].

3.11 preferred term: Term recommended by an authoritative body [ISO 1087:1990].

3.12 primary key: A key that unambiguously identifies one record [ISO/IEC 2382-17:1996].