Irish Standard
I.S. EN ISO 15225:2016

Medical devices - Quality management - Medical device nomenclature data structure (ISO 15225:2016)

I.S. EN ISO 15225:2016

Incorporating amendments/corrigenda/National Annexes issued since publication:

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I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

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National Foreword

I.S. EN ISO 15225:2016 is the adopted Irish version of the European Document EN ISO 15225:2016, Medical devices - Quality management - Medical device nomenclature data structure (ISO 15225:2016)

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In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15225

April 2016

ICS 01.040.11; 01.040.35; 11.040.01; 35.240.80

Supersedes EN ISO 15225:2010

English version

Medical devices - Quality management - Medical device nomenclature data structure (ISO 15225:2016)

Dispositifs médicaux - Management de la qualité - Structure des données de nomenclature des dispositifs médicaux(ISO 15225:2016)

Medizinprodukte - Qualitätsmanagement - Datenstruktur für die Nomenklatur von Medizinprodukten (ISO 15225:2016)

This European Standard was approved by CEN on 9 June 2016.

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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 and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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European foreword

This document (EN ISO 15225:2016) has been prepared by Technical Committee ISO/TC 210 “Quality management and corresponding general aspects for medical devices” in collaboration with Technical Committee CEN/CLC/TC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

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 October 2016, and conflicting national standards shall be withdrawn at the latest by October 2016.

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

This document supersedes EN ISO 15225:2010.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 15225:2016 has been approved by CEN as EN ISO 15225:2016 without any modification.

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I.S. EN ISO 15225:2016

INTERNATIONAL STANDARD

ISO 15225

Third edition
2016-03-15

Medical devices — Quality management — Medical device nomenclature data structure

Dispositifs médicaux — Management de la qualité — Structure des données de nomenclature des dispositifs médicaux

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This third edition of this International Standard based on experience gained from utilization of the second edition cancels and replaces the second edition (ISO 15225:2010), which has been technically revised. The following major changes have been made:

— Template terms have been removed as the hierarchy within the GMDN is now managed with the use of 'collective terms'.

— 'Device category' has been removed as this provides no benefit for navigation and its value has now been superseded by the use of 'collective terms'.

— The prefix 'preferred' has been removed from term in the document and the word 'term' now denotes the primary identifier for generic device groups of medical devices.

— 'Collective terms' can now be used by medical device regulators and other users to select larger groups of medical devices and analyse larger sets of data. 'Terms' however remain the only way to identify generic device groups of medical devices.

— 'Device type' data specification has been removed as it is outside the scope of the GMDN dataset, but remains a concept to which GMDN data are linked.

Introduction

This International Standard is intended to assist competent authorities, conformity assessment bodies, healthcare providers and manufacturers in the submission and exchange of information. It is intended that the information covered by this International Standard be available in the public domain.

This third edition of this International Standard is based on experience gained from utilization of the second edition.

The requirements contained in this International Standard are applicable to the development and updating of an international nomenclature and have been prepared specifically for construction of the Global Medical Device Nomenclature (GMDN).

Medical devices — Quality management — Medical device nomenclature data structure

1 Scope

This International Standard specifies rules and guidelines for a medical device nomenclature data structure, in order to facilitate cooperation and exchange of data used by regulatory bodies on an international level between interested parties, e.g. regulatory authorities, manufacturers, suppliers, healthcare providers and end users.

This International Standard includes guidelines for a minimum data set and its structure. These guidelines are provided for system designers setting up databases that utilize the nomenclature system described herein.

The requirements contained in this International Standard are applicable to the development and maintenance of an international nomenclature for medical device identification.

This International Standard does not include the nomenclature itself, which is provided as a separate data file.

2 Normative references

The following documents, in whole or in part, are normatively referenced in the document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 8859-1:1998, *Information technology — 8-bit single-byte coded graphic character sets — Part 1: Latin alphabet No. 1*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply[1)].

3.1
character
member of a set of elements used for the organization, control or representation of data

[SOURCE: ISO/IEC 8859-1:1998, 4.3]

3.2
code
system of alpha, alphanumeric or numeric characters and rules by which information is represented, communicated, or both

3.3
collective term
term provides a multi-hierarchical structure to search for appropriate generic device group terms by using broad common features or characteristics

1) In this International Standard, many terms are used which have their basis in regulatory statutes, e.g. “medical device”, “custom made medical device” and “manufacturer”. These terms are defined in the respective jurisdictions where the nomenclature is used.