

DRAFT INTERNATIONAL STANDARD

ISO/DIS 15225

ISO/TC 210

Secretariat: ANSI

Voting begins on:
2015-07-23

Voting terminates on:
2015-10-23

Medical devices — Quality management — Medical device nomenclature data structure

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

ICS: 11.040.01; 35.240.80

ITeH STANDARD PREVIEW
(standards.iteh.ai)
Full standard:
<https://standards.iteh.ai/catalog/standards/sist/031f62e-3e72-438c-9500-a891e2b62a91/iso-15225-2016>

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.



Reference number
ISO/DIS 15225:2015(E)

© ISO 2015

iTeh STANDARD PREVIEW
(standards.iteh.ai)
Full standard:
<https://standards.iteh.ai/catalog/standards/sist/031f62e-3e72-438c-9500-a891e2b62a91/iso-15225-2016>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2015, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword	iv
Introduction.....	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Principle of structure	3
4.1 General	3
4.2 Term	4
4.2.1 Description	4
4.2.2 Term name.....	4
4.2.3 Term definition.....	4
4.2.4 Term code.....	4
4.2.5 Links to relevant collective term(s) (see 4.3).....	4
4.2.6 Links to synonym(s).....	4
4.2.7 Links to multiple-linked synonym(s).....	5
4.3 Collective term	5
4.4 Nomenclature structure example.....	5
4.5 Synonyms.....	5
4.6 Multiple-linked synonyms.....	5
4.7 Abbreviations and acronyms	6
5 Data file dictionary	6
5.1 General	6
5.2 Term data file	7
5.3 Collective term data file	7
Annex A (informative) Examples for generation of generic device group terms and synonyms.....	8
Annex B (informative) Example of term record	10
Annex C (informative) Examples of collective terms	11
Annex D (informative) Examples of top level collective term nodes.....	12
Bibliography.....	13

Error! Reference source not found.

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.

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

This third edition cancels and replaces the second edition, which has been technically revised.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
Full standard available at
<https://standards.iteh.ai/catalog/standards/sist/31f62e-3e72-438c-9500-a891e2b62a91/iso-15225-2015>

1 Introduction

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

5 This third edition of this International Standard is based on experience gained from utilization of the second
6 edition. The following major changes have been made to the second edition:

7 — Template terms have been removed as the hierarchy within the GMDN is now managed with the use of
8 Collective terms;

9 — Device Category has been removed as this provides no benefit for navigation and its value has now been
10 superseded by the use of Collective terms.

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

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

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

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Full standard:
<https://standards.iteh.ai/catalog/standards/sist/031f62e-3e72-438c-9500-a891e2b62a91/iso-15225-2016>

21 Medical devices — Quality management — Medical device nomenclature structure

22 1 Scope

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

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

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

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

32 2 Normative references

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

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

38 3 Terms and definitions

39 For the purposes of this document, the following terms and definitions apply¹⁾.

40 3.2 41 character

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

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

44 3.3 45 code

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

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 are used.

Error! Reference source not found.

48 **3.4**
49 **collective term**
50 term provides a multi-hierarchical structure to search for appropriate generic device group terms by using
51 broad common features or characteristics

52 **3.5**
53 **concept**
54 unit of knowledge created by a unique combination of characteristics

55 [SOURCE: ISO 1087-1:2000, 3.2.1]

56 **3.6**
57 **definition**
58 formal concise statement of the meaning of a term

59 **3.7**
60 **device intended for clinical investigation**
61 device intended for use in a designed and planned systematic study in or on human subjects to verify the
62 safety, performance, or both

63 **3.8**
64 **device intended for performance evaluation**
65 device intended by the manufacturer to be subject to performance evaluation studies in laboratories for
66 medical analyses or other appropriate environments outside the manufacturer's premises

67 **3.9**
68 **device type**
69 identification of a manufacturer's specific kind of products, i.e., for similar usage or series of comparable
70 models

71 NOTE This data element is not included in the GMDN nomenclature, but is coded in various ways outside
72 of the nomenclature and linked to terms.

73 **3.10**
74 **file**
75 named set of records stored or processed as a unit

76 [SOURCE: ISO/IEC 2382-1:1993, 01.08.06]

77 **3.12**
78 **generic device group**
79 set of devices having the same or similar intended use and common technology, identified by a term

80 **3.13**
81 **Global Medical Device Nomenclature**
82 **GMDN**
83 nomenclature based on the structure of this International Standard, which provides information in the form of
84 a code to indicate the generic descriptor within which a device type can be identified

85 NOTE By reference to this globally accepted, generic medical device nomenclature, other particular devices which
86 have substantially similar generic features but which come from another source can be identified, for reasons of data
87 exchange between competent authorities and others, for the exchange of post-market vigilance information and for
88 inventory purposes.

89 **3.14**
90 **GMDN agency**
91 organization representing the interests of regulatory agencies, manufacturers and healthcare providers to
92 ensure the continued relevance and effectiveness of the GMDN, and is responsible for the development,
93 control and distribution of the GMDN

94 **3.15**
95 **identifier**
96 <organization of data> one or more characters used to identify or name a data element and possibly to
97 indicate certain properties of that data element

98 [SOURCE: ISO/IEC 2382-4:1999, definition 04.09.02]

99 **3.16**
100 **multiple-linked synonym**
101 alternative name(s) for a synonym term linked to more than one GMDN Term

102 [SOURCE: GMDN Agency]

103 **3.17**
104 **name**
105 verbal designation of an individual concept

106 [SOURCE: ISO 1087-1:2000, 3.4.2, modified — .]

107 **3.18**
108 **nomenclature**
109 terminology structured systematically according to pre-established naming rules

110 [SOURCE: ISO 1087-1:2000, 3.5.3]

111 **3.21**
112 **product identifier**
113 marker to indicate which terms can and cannot be used for product identification

114 [SOURCE: GMDN Agency]

115 **3.24**
116 **synonym**
117 alternative name for a term

118 EXAMPLE a proprietary or common name for a device

119 **3.25**
120 **term**
121 the basic data entity within the GMDN dataset

122 NOTE A term consists of a code, name and definition. It is the data representation of a generic device group.

123 [SOURCE: ISO 1087-1:2000, 3.4.3, modified — .]

124 **3.26**
125 **Unique Device Identification**
126 **UDI**
127 a unique number assigned to a device type

128 **4 Principle of structure**

129 **4.1 General**

130 The nomenclature shall consist of terms, collective terms, synonyms and multiple-linked synonyms. All
131 elements have codes and names, and terms additionally have definitions. All terms should be given in the
132 singular form.