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AMENDMENT 1
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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
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Foreword

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

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

AMENDMENT 1

Page 7, Subclause 5.2.2

Add the following new paragraph at the end of this subclause:

"Any abbreviation being adopted should be in widely recognized terminology."

Page 7, Subclause 5.2.3

Add the following immediately under b):

"A comma and one space shall delimit each additional qualifier.

EXAMPLES Applicator, brachytherapy, remote afterloading, bladder."

Page 9, Subclause 6.1

Change "NOTE" to "NOTE 1".

Immediately following NOTE 1, add the following NOTES:

"NOTE 2 Each stage in the data structure is represented by a data file for which the requirements in 6.2 to 6.4 apply. The requirements herein defined are a commonly prescribed method used in relational databases for linking data files (see also Annex C). The system designer should apply appropriate methods available in the database tool to achieve an equal functionality for the nomenclature. If an alternative coding structure is used, it should not restrain the use of GMDN within various database environments, e.g. SQL, Server, Oracle, Sybase, etc.

NOTE 3 In Tables 1 and 2, the format for the definition is given as 18×70 characters (Table 1) and 10×70 (Table 2). It is for the information system designers implementing the nomenclature to decide whether a format of lines of 70 characters in length, or a singular data string of 1 260 characters (Table 1) or 700 characters (Table 2) is most suitable."

Page 10, Subclause 6.3

In Table 2, column 2, line 3, replace "60" with "120".

Page 17, Annex B

Under **Example of style**, add the following at the end of the text:

"Capital letters may be used in the generic device group term when they represent the accepted terminology.

EXAMPLES	Inventor's name	Von Frey hairs
	Chemical symbol	Sample transport, Na testing calibrator
	Device name	X-ray tube support, C-arm

Punctuation

Clause 6, Data file dictionary, Subclause 6.1 defines the character set to be used when implementing the nomenclature within a database. The developers of the Global Medical Device Nomenclature (GMDN) have adopted the following punctuation for use in the GMDN as legal character elements used in generic device group names or in the definitions:

comma (,)	used as a delineator or comma
hyphen (-)	used to create compound words
forward slash (/)	means “and” alternatively “or”
apostrophe (′)	used in some chemical names or as an apostrophe
plus character (+)	used in some chemical names.”

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