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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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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

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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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.

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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).