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Global medical device nomenclature for the purpose of regulatory data exchange

Nomenclature globale des dispositifs médicaux destinée à l'échange de données réglementtaires

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

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An ISO/PAS or ISO/TS is reviewed after three years with a view to deciding whether it should be confirmed for a further three years, revised to become an International Standard, or withdrawn. In the case of a confirmed ISO/PAS or ISO/TS, it is reviewed again after six years at which time it has to be either transposed into an International Standard or withdrawn.

Attention is drawn to the possibility that some of the elements of this Technical Specification may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TS 20225 was prepared by the European Committee for Standardization (CEN) in collaboration with Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Throughout the text of this document, read "...this Report..." to mean "...this Technical Specification...".

Foreword

This CEN Report was prepared by 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 ISO/TC 210, *Quality management and corresponding general aspects for medical devices.*

This is a first edition, so no other documents are superseded.

This document was prepared by CEN/TC 257/SC1, *Identification, coding, Nomenclature and regulatory data sets for medical devices,* in collaboration with ISO/TC 210, *Quality management and corresponding general aspects for medical devices*

Annex A is for information only.

This CEN Report contains a Bibliography.

Introduction

This technical report contains the Nomenclature for medical devices for the purpose of regulatory data exchange. Whereas the nomenclature may be useful for other purposes, it is designed and was developed for regulatory data exchange, such as vigilance reporting, tracking of medical device safety. It may also have other applications such as regulatory registrations.

Generic device groups have been identified for those devices which are characterised as devices in regulations of all the various jurisdictions as the laws relevant to medical devices define them. However, some jurisdictions may not consider a particular device to be a medical device for their respective jurisdiction. Simply because the device is listed in this nomenclature does not necessarily mean it is a medical device in every jurisdiction.

This technical report includes the complete nomenclature at the time of publication. Medical devices are listed alphabetically by their generic device group name with the respective code and definition. Additionally, synonyms for medical devices make reference to the appropriate generic device group. For details of the complete structure, please refer to EN ISO 15225 *Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange*. It is anticipated that the report will be available in due course from standards organisations as an image file on digital media.

A Maintenance Agency is being established to meet the need for timely consideration of new terms and definitions or revisions of current terms and definitions. New terms will be accepted periodically as required and the list in this report may not be fully up to date. Please refer to supplements issued periodically by the Agency to ensure that you have the most up to date version.

The nomenclature will also be available in an electronic format, for example in digital format as an image file. The electronic format will conform to EN ISO 15225, however it will be updated more frequently than this report.

For more information regarding this process, other information such as a current list of database licensees and official translations, or advice and help with new terms, contact the Global Medical Device Nomenclature Maintenance Agency. Find details about the Agency on:

< http://www.bsi-global.com/gmdn >

or contact your local standards authority.

1 Scope

This Report lists terms, definitions and codes for medical devices; the listing is structured such that it can be used for the purpose of regulatory data exchange.