Second edition
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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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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 second edition cancels and replaces the first edition (ISO 15225:2000), which has been technically revised. It also incorporates the Amendment ISO 15225:2000/Amd.1:2004.

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

— definitions have been added in Clause 3 for base concept, collective term, device category, device type, generic device group, Global Medical Device Nomenclature (GMDN), GMDN agency, multiple-linked synonym, product specifier and template specifier;

— Codes 13, 14 and 15 have been added in Annex A, and the descriptions have been updated with examples of new technologies;

— Annex D has been added containing examples of collective terms.

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).