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Nomenclature - Collective terms and codes for groups of medical devices

Nomenclature - Termes et codes collectifs pour les groupes de dispositifs médicaux

Nomenklatur - Sammelbegriffe und Kodes für Gruppen von Medizinprodukten

This Technical Report was approved by CEN on 6 May 2005. It has been drawn up by the Technical Committee CEN/TC 257.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

This document (CEN/TR 15133:2005) has been prepared by Technical Committee CEN/TC 257 “Symbols and information provided with medical devices and nomenclature for regulatory data exchange”, the secretariat of which is held by SFS.

This CEN report has been prepared under the mandate (M321) given to CEN by the European Commission and the European Free Trade Association.

This CEN Report is intended to complement the specific requirements of the EU regulations on medical devices relating to information exchanged between parties communicating in conformity with requirements of the Directives.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this CEN Technical Report: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Introduction

This Technical Report contains collective terms for those medical devices which share common features and are identified in the Global Medical device Nomenclature (GMDN), published as CR 14230:2001 *Global medical device nomenclature for the purpose of regulatory data exchange (identical to ISO/TS 20225:2001* Whereas the GMDN is designed and was developed for regulatory data exchange in areas such as vigilance reporting and tracking of medical device safety, there is a need for a set of terms that are more refined than the GMDN category terms, yet broader than the GMDN generic device group terms, to be used in the application of the medical device directives where the use of collective terms provides adequate identification.

These collective terms are intended to be used for example:

— to illustrate the scope of certificates issued by Notified Bodies when assessing which groups, families or types of medical devices are covered within a manufacturer's quality system,

— to be used to identify the range of skills and general technological abilities for which a Notified Body has been approved, and is so appointed by the relevant Competent Authority,

— for the exchanges of information between Competent Authorities when general information on individual manufacturers capabilities is notified for inclusion in the European Database for Medical Devices (EUDAMED).

These terms, named "collective terms", are appropriate for providing general groupings to meet, in particular, the above identified requirements.

In the preparation of this CEN REPORT a number of principles were identified which were used in grouping together generic device group terms of the GMDN within the proposed "collective terms". These were:

— Devices covered by the application of common technology

— Devices manufactured using similar manufacturing procedures, and with common technical features.

— Devices manufactured for the application of similar Medical Procedures

— Devices manufactured using common materials requiring special skills.

— Devices developed to meet specific risk-associated considerations.

For ease of electronic transmission of data, and to eliminate the possibility of confusion with other coding systems having a three-digit code used for information concerning Medical Devices, each collective term is assigned a three-digit random code with the prefix "CT" (Collective Term), which identifies the code source.

It is expected that as the collective terms are brought into use, they will be assigned to the generic device group terms of the GMDN. The Maintenance Agency (MA) of the GMDN will make these links available. Details of progress in this area will be posted on the MA web site at http://www.gmdn.org.

1 Scope

This Technical Report lists collective terms and codes for groups of medical devices having common features. The listing is structured so that the terms can be used for the purposes required in regulatory reporting and for communication relevant to the application of the medical device regulation.

For certain purposes in the application of the Medical Devices Directives, there is an urgent need for the development of a list of collective terms based on the identified principles to be used, for examples, as follows:

— to illustrate the scope of certificates issued by Notified Bodies when assessing which groups, families or types of medical devices are covered within a manufacturer's quality system,

— to be used to identify the range of skills and general technological abilities for which a Notified Body has been approved, and is so appointed by the relevant Competent Authority,

— for the exchanges of information between Competent Authorities when general information on individual manufacturers capabilities is notified for inclusion in the European Database for Medical Devices (EUDAMED).

For the purpose of developing sets of collective terms, Accessories to medical devices are integrated de facto in the corresponding medical device collective term.

2 Lists of collective terms

NOTE 1 Any specific Generic Device term from the GMDN may be assignable to more than one of the collective terms listed here.

NOTE 2 When assigning collective terms for any of the particular uses outlined in the Introduction, more than one collective term may be assigned, if required, to improve the definition of the specified circumstances under which the assignment is being made.

NOTE 3 The collective term(s) selected for any set of circumstances should cover the broadest scope in the grouping for which a selection is required so that the smallest set of collective terms that will describe the situation will be the one used.

NOTE 4 When using the collective term codes to communicate information, the "CT" prefix must be used to identify the code source.

2.1 Application of Common Technology

Any specific Generic Device group term from the GMDN shall be assignable to at least one of the collective terms listed as "Common technology".

ct code	Collective Terms	Applicable GMDN Categories		
		1	2	3
CT: 231	Ablation devices	9	10	
CT: 005	Absorbable implants	7	3	