

Devices, each collective term is assigned a three-digit random code with the prefix "CT" (Collective Term), which identifies the code source.

It is anticipated that as the collective terms are brought into use, attributes may be assigned to the generic device group terms of the GMDN and not to the collective terms. 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 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 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 manufacturers 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. Listing of collective terms: 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 here.

Note 1. 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 for which the assignment is being made.

Note 2. 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 is the one used.

Note 3. Category codes from the GMDN (see EN ISO 15225:2000) are listed to assist in the correct assignment of collective terms.

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

Code	Collective Terms	Cat 1	Cat 2	Cat 3
CT: 005	Absorbable implants	7		
CT: 192	Accelerator systems	12		
CT: 006	Acoustic chambers	4		
CT: 128	Active implantable devices	1		
CT: 007	Airways/respiratory system	10		
CT: 008	Ambulance & ancillary devices	5		
CT: 009	Anaesthesia units/work stations and ancillary devices	2		
CT: 129	Anaesthetic and Respiratory devices	2		
CT: 010	Analgesia devices	2		
CT: 195	Analyzers, clinical chemistry	6		
CT: 011	Angioplasty systems/devices	10		
CT: 012	Bandages	10		

Code	Collective Terms	Cat 1	Cat 2	Cat 3
CT: 013	Bedding/mattresses/pillows	5	12	
CT: 102	Beds for medical purposes	11		
CT: 096	Blood collecting devices	10		
CT: 071	Blood flow measurement devices	4	12	
CT: 066	Blood gas analyzers	4	6	
CT: 014	Blood pressure measuring devices invasive/non invasive	4		
CT: 097	Blood transfusion sets	10		
CT: 162	Bone cements	10		
CT: 163	Bone remineralisation devices	10		
CT: 193	Brachytherapy devices	12		
CT: 091	Breast implants	7		
CT: 070	Cardiac output measuring devices	4	12	
CT: 145	Cardiovascular devices	7		
CT: 015	Catheters	10	4	7
CT: 095	Cell & tissue collection devices	10		
CT: 196	Centrifuges	6		
CT: 123	Cochlear implants	1		
CT: 016	Computer Tomograph (CT), and ancillary devices	12		
CT: 017	Contact lenses, corrective & lens care products	8		
CT: 018	Contraceptive devices	10		
CT: 164	Cornea prosthesis	8		
CT: 126	Correcting spectacles	8		
CT: 078	Cryosurgical, devices	4		
CT: 074	Defibrillators external	4		
CT: 062	Defibrillators, implantable	1		
CT: 019	Dental equipment - non powered	3		
CT: 020	Dental equipment - powered	3		

Code	Collective Terms	Cat 1	Cat 2	Cat 3
CT: 130	Dental devices	3		
CT: 003	Dental implants	3	7	
CT: 064	Dental materials	3		
CT: 124	Dental orthodontic devices	3		
CT: 004	Dental prosthesis	3		
CT: 001	Dental, instruments, non-powered	3		
CT: 002	Dental, instruments, powered	3	4	
CT: 176	Diagnostic and therapeutic radiation devices	12		
CT: 100	Dialysis devices / Haemodialysis/haemofiltration	10		
CT: 045	Dialysis devices, peritoneal	10	4	
CT: 022	Distension units	9		
CT: 131	Electro mechanical medical devices	4		
CT: 024	Electro therapy equipment	4		
CT: 068	Electrocardiographs (ECG equipment)	4		
CT: 025	Electroconvulsive therapy units	4		
CT: 026	Electrodes & biosensor	4		
CT: 023	Electroencephalographs (EEG equipment)	4		
CT: 065	Endoscopes & endoscopic devices	4		
CT: 027	Enteral feeding devices, including dedicated pumps	4	10	
CT: 219	Gas supply system & ancillary devices			
CT: 142	Genetic testing devices	6		
CT: 049	Gloves	10		
CT: 029	Gynaecological/obstetrical devices	9		
CT: 030	Haemostatic materials	10		
CT: 101	Hearing aids	11	1	
CT: 088	Heart valves	7		
CT: 031	Heart-Lung bypass systems	1	4	

Code	Collective Terms	Cat 1	Cat 2	Cat 3
CT: 132	Hospital hardware	5		
CT: 077	Hyperthermia system and ancillary for malignant tumor: growth treatment	4	12	
CT: 032	Hypothermia/hyperthermia device for body temperature regulation	5		
CT: 133	In Vitro Diagnostic, other	6		
CT: 075	Incubators, infant	4		
CT: 218	Incubators, laboratory	4	6	
CT: 073	Infusion pumps	4		
CT: 063	Infusion pumps, implantable	1		
CT: 033	Intraocular implants	7		
CT: 034	Intravenous administration sets	10		
CT: 035	Iontophoresis equipment	4		
CT: 083	Irrigation & Lavage equipment	5		
CT: 036	Lasers for medical use	4		
CT: 220	Leucodepletion device	10		
CT: 220	Lifts for patient/person transfer			
CT: 037	Lithotriptors	4		
CT: 105	Magnetic Resonance Imaging equipment (MRI)	12		
CT: 038	Magnetic therapy units	4		
CT: 079	Massage equipment	4		
CT: 039	Medical gas supply devices (portable)	2		
CT: 216	Microscopes	6		
CT: 127	Microscopes, surgical	5		
CT: 084	Nebulizers for liquid or powder dispersal, Inhalers	2		
CT: 098	Needles	10		
CT: 040	Neurological diagnostic equipment	4		
CT: 134	Non-Active implantable devices	7		
CT: 106	Nuclear medicine equipment	12		

Code	Collective Terms	Cat 1	Cat 2	Cat 3
CT: 165	Ocular prosthesis	8		
CT: 085	Operating theatre lighting	5		
CT: 041	Operating theatre tables & other patient supporting systems for medical interventions.	5	12	3
CT: 135	Ophthalmic and optical devices	8		
CT: 042	Ophthalmological, measuring, testing, surgical, instruments	8	4	
CT: 166	Oral surgical fixation/distraction devices	3		
CT: 125	Orthopaedic implants, joints	7		
CT: 043	Ostomy devices	10		
CT: 076	Pacemaker, cardiac, external	4		
CT: 061	Pacemakers, cardiac, implantable	1		
CT: 050	Patient monitoring systems/devices, respiratory	2	4	
CT: 046	Phototherapy devices	4		
CT: 080	Physiotherapy diathermy equipment	4		
CT:221	Picture archiving and communication system			
CT: 047	Pressure alleviation devices	5		
CT: 048	Prosthesis for augmentation/replacement of body parts	7		
CT: 108	Radiation Protection devices	12		
CT: 104	Radiological diagnostic equipment i.e. X-ray)	12		
CT: 109	Radiotherapy equipment	12		
CT: 136	Reusable instruments	9		
CT: 197	Scales	6		
CT: 194	Simulators, radiotherapy	12		
CT: 137	Single use devices	10		
CT: 112	Software for medical purposes	4	6	12
CT: 169	Software, diagnostic	4		
CT: 051	Speech therapy devices	4		
CT: 052	Sponges/swabs	10		
CT: 215	Staining devices	6		

Code	Collective Terms	Cat 1	Cat 2	Cat 3
CT: 094	Stapling/Suturing devices	9	10	
CT: 090	Stents	7		
CT: 086	Sterilizer/Disinfection devices	5		
CT: 072	Stethoscopes	4		
CT: 053	Stimulators, - muscle/nerve	4		
CT: 110	Stimulators, muscle/nerve, implantable	1		
CT: 082	Suction units & drainage devices	5	7	3
CT: 021	Surgical diathermy devices	4		
CT: 093	Surgical instruments	9		
CT: 055	Surgical instruments - powered	4		
CT: 056	Surgical instruments, micro	10		
CT: 111	Syringe pumps	4		
CT: 099	Syringes & Injectors	10	12	3
CT: 138	Technical aids for disabled persons	11		
CT: 069	Thermometers, clinical	4		
CT: 057	Tracheotomy tubes	10		
CT: 058	Training aids/models/devices for re-educational purposes	11	10	
CT: 059	Transducers	4	12	
CT: 107	Ultrasonic diagnostic equipment	12		
CT: 081	Ultrasonic therapy equipment	4		
CT: 089	Vascular implants	7		
CT: 060	Ventilators, respiratory	2	4	
CT: 103	Walking and other mechanical aids for disabled	11		

3. Listing of collective terms: Using similar manufacturing procedures

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

Note 1. 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 for which the assignment is being made.

Note 2. 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 is the one used.

Note 3. Category codes from the GMDN (see EN ISO 15225:2000) are listed to assist in the correct assignment of collective terms.

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

Code	Collective Terms	Cat 1	Cat 2	Cat 3
CT: 191	Blood banking technology			
CT: 187	Chemical synthesis			
CT: 213	Clinical chemistry	6		
CT: 171	Electronic design			
CT: 172	Growth media, processes			
CT: 190	Medical gas technology			
CT: 177	Metal fabrication			
CT: 178	Optics fabrication			
CT: 179	Plastics fabrication			
CT: 181	Radio immunoassay			
CT: 180	Rubber fabrication			
CT: 182	Serology			
CT: 170	Software development			
CT: 143	Sterilization (gas, EtO, dry heat, steam, chemical)	20		
CT: 185	Textile fabrication			
CT: 189	Tissue engineering - animal			

Code	Collective Terms	Cat 1	Cat 2	Cat 3
CT: 188	Tissue engineering - human			
CT: 184	Toxicology			
CT: 186	Wood fabrication			

4. Listing of sub categories: For similar medical procedures

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

Note 1. 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 for which the assignment is being made.

Note 2. 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 is the one used.

Note 3. Category codes from the GMDN (see EN ISO 15225:2000) are listed to assist in the correct assignment of collective terms.

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

Code	Collective Terms
CT: 144	Anaesthesiology
CT: 195	Analyzers, clinical chemistry
CT: 145	Cardiovascular devices
CT: 213	Clinical chemistry
CT: 161	Clinical toxicology
CT: 146	Dental/Dentistry
CT: 219	Dermatology
CT: 147	Ear, Nose, & Throat (ENT)
CT: 175	Endocrinology
CT: 148	Gastroenterology
CT: 160	General & plastic surgery
CT: 149	General hospital
CT: 228	Genetic Testing
CT: 214	Haematology/histology/cytology
CT: 139	Immunochemistry
CT: 152	Immunology, infectious
CT: 141	Infectious Immunology
CT: 140	Microbiology
CT: 151	Microbiology, culture
CT: 153	Neurology
CT: 221	Neuropsychiatry
CT: 154	Obstetrics/Gynecology
CT: 155	Ophthalmology

Code	Collective Terms
CT: 156	Orthopaedic
CT: 157	Pathology
CT: 222	Pediatrics
CT: 158	Physical medicine
CT: 223	Pneumology
CT: 159	Radiology
CT: 173	Radiotherapy
CT: 224	Rhumatology
CT: 174	Stomatology
CT: 218	Surgery
CT: 220	Urology

5. Listing of sub categories: Using common materials

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

Note 1. 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 for which the assignment is being made.

Note 2. 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 is the one used.

Note 3 Category codes from the GMDN (see EN ISO 15225:2000) are listed to assist in the correct assignment of collective terms.

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

Code	Collective Terms
CT: 210	Animal materials
CT: 207	Biological active coatings
CT: 208	Biological materials
CT: 203	Ceramics
CT: 206	Composites
CT: 209	Human materials
CT: 202	Metals
CT: 204	Natural rubber latex
CT: 201	Polymers
CT: 205	Radio-active materials
CT: 212	Silicones
CT: 211	Vegetable materials

6. Listing of sub categories: specific risk-associated considerations

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

Note 1. 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 for which the assignment is being made.

Note 2. 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 is the one used.

Note 3. Category codes from the GMDN (see EN ISO 15225:2000) are listed to assist in the correct assignment of collective terms.

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

Code	Collective Terms
CT: 121	Devices for self-diagnosis, including its related calibrators and control materials: devices for the measurement of blood sugar
CT: 122	Devices for self-testing, other than for blood sugar
CT: 133	In Vitro Diagnostic, other
CT: 116	Reagents and reagent products, including related calibrators and control materials, for determining irregular anti-erythrocytic antibodies
CT: 119	Reagents and reagent products, including related calibrators and control materials, for determining the HLA tissue groups DR, A, B
CT: 115	Reagents and reagent products, including related calibrators and control materials, for determining the blood group anti-Duffy and anti-Kidd
CT: 113	Reagents and reagent products, including related calibrators and control materials, for determining the blood groups ABO system, rhesus (C, c, D, E, e) anti-Kell
CT: 118	Reagents and reagent products, including related calibrators and control materials, for determining the following human infections: cytomegalovirus, chlamydia
CT: 226	Reagents and reagent products, including related calibrators and control materials, for determining the following tumoral marker: PSA
CT: 225	Reagents and reagent products, including related calibrators and control materials, for diagnosing the following hereditary disease: phenylketonuria
CT: 117	Reagents and reagent products, including related calibrators and control materials, for the detection and quantification in human of the following congenital diseases: rubella, toxoplasmosis
CT: 114	Reagents and reagent products, including related calibrators and control materials, for the detection, phenotyping/genotyping, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D
CT: 120	Reagents and reagent products, including related calibrators, control materials and software, designed specifically for evaluating the risk of trisomy 21

BIBLIOGRAPHY

EN ISO 15225:2000 Nomenclature - Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange

CR 14230:2001 Global medical device nomenclature for the purpose of regulatory data exchange (identical to ISO/TS 20225:2001)

CEN/TC 257/WG 4 documents :-

<u>Document No.</u>	<u>Description</u>
N 6	Proposal for sub categories for dental devices (Source: EN 1639,1640,1641,1642 & CEN/TR 12401)
N 7	Proposal communicated by Leighton Hansel (Source: US CDRH Device Profile Class Codes)
N 8	GMDN Maintenance Agency Expert Team-Product Categories Draft 3 (Source: Sub categories for medical devices. M F Freeman)
N 9	Codification ICS (International Classification for Standards)
N 10	Template terms from the GMDN.
N 11	UNSPSC medical equipment and accessories sub categories (Source: UN hospital product supply codes, segment 42))
N XX	JFDA sub categories
N YY	Medipub Luxembourg

ICS 11.040

英語版

命名法-規制当局への報告および医療用具規制の申請における情報伝達を目的とした、共通特性を有する一群の医療用具に関する包括的命名法中の集合語およびコード

目次	ページ
序文.....	3
緒言.....	4
1. 適用範囲.....	7
2. 集合語の一覧：共通技術の適用.....	8
3. 集合語の一覧：同様の製造手順を用いるもの.....	13
4. サブカテゴリーの一覧：同様の医療処置を目的とするもの.....	15
5. サブカテゴリーの一覧：共通材料を用いるもの.....	17
6. サブカテゴリーの一覧：特異的なリスクに関連した検討事項.....	18
参考文献.....	20

序文

このCEN報告書は、専門委員会CEN/TC 257（医療用具とともに提供される記号と情報および規制データ交換のための命名法）によってCEN/TC 257/WG 4サブカテゴリーを通じて作成された。CEN/TC 257およびTC 257/WG 4の事務局はSFSによって開催される。

このCEN報告書は、欧州委員会および欧州自由貿易連合がCENに与えた指令（M321）に従って作成された。

このCEN報告書は、指令の要件に従って情報伝達を行なう当事者間で交換される情報に関して、医療用具に関するEU規制の特異的要件を補足することを目的としている。

緒言

この専門報告書には、包括的医療用具命名法（Global Medical Device Nomenclature; GMDN）に特定され、共通の特性を有する医療用具の集合語が含まれる。GMDNはCR 14230:2001 *Global medical device nomenclature for the purpose of regulatory data exchange (ISO/TS 20225:2001と同一)* として発表されている。GMDNは監視報告および医療用具の安全性に関する追跡等の分野における規制データ交換のため設計、作成されたが、医療用具指令の申請では集合語の使用によって適切な識別が可能となり、このような申請において使用するためには、GMDNカテゴリー用語よりも正確であり、さらにGMDNジェネリック医療用具分類用語よりも広範囲にわたる用語が必要とされている。

これらの集合語は以下のような例での使用を目的としている：

- 製造業者の品質システムの範囲内に該当する医療用具のグループ、ファミリーまたは種類を判定する際、届出機関によって発行された証明書の範囲を示す
- 届出機関が承認し、それをうけて関係監督官庁が指定した技能および一般技術能力の範囲を特定するために用いる
- 欧州医療用具データベース（EUDAMED）への登録のため、個々の製造業者の能力に関する一般的情報の届出があった場合、監督官庁間で情報を交換するために用いる

これらの用語（すなわち「集合語」）は、特に上記の要件を満たすための一般的分類に適している。

このCEN報告書の作成にあたり、「集合語」案の範囲内において、GMDNのジェネリック医療用具分類用語とともに、分類に用いられる多数の原則が特定された。これらの内訳は以下の通りであった：

- 共通技術の応用によってカバーされる医療用具
- 同様の製造手順を用いて製造され、共通の技術特性を有する医療用具
- 同様の医療処置の適用を目的として製造された医療用具
- 特殊技能を必要とする共通材料を用いて製造された医療用具

- 特異的なリスクに関する検討事項を満たすために開発された医療用具

データの伝送を容易にするとともに、医療用具に関する情報に用いられる3桁コードの他のコーディングシステムと混乱が生じる可能性を排除するため、各集合語にはコードソースを特定する接頭辞「CT」（集合語）の付いた3桁のランダムコードが割り当てられている。