

The Global Medical Device Nomenclature (GMDN):

The following pages have been formulated by NKKN for the purpose of promoting the GMDN and providing the latest up to date information about it. This information is available in English only.

FUNCTION OF THE GMDN

Medical devices are varied and complex. An essential requirement for the healthcare environment, where the free movement of medical devices is a substantial part of world trade, is the attainment of the highest possible level of patient safety. One of the important elements being established to achieve this is the so-called Vigilance systems. This procedure establishes investigation and assessment of reported incidents which have either caused, or might have caused, death or serious injury to patients using a medical device.

This will relate to organizations involved in the regulatory process by which manufacturers put products on the market, for example in the European Economic Area (EEA), data concerning CE mark authorisation certificates granted, refused or withdrawn by Notified Bodies (NB). Another particularly important example concerns the protection of public health when data is exchanged about adverse incidents involving medical devices where patient's or healthcare worker's welfare can be jeopardized. These all need a system for unambiguously identifying the medical device concerned.

In addition, the bilateral mutual recognition agreements set up by the European Union with Australia, Canada, New Zealand and USA each incorporate the exchange of regulatory information.

To assure precise communication of regulatory data on a world-wide basis it is necessary to have a globally recognized system of terms to identify, analyse, track, and determine the reported events. The objective of the GMDN is to establish such a set of terms: "Generic Device Groups" that, when arranged in a data system, will facilitate electronic communication, between the EU member states and other international bodies/markets.

The European standards organization, CEN, set up a multinational project to develop a global nomenclature for medical devices. It was called the ([GMDN Project](#)). The outcome, now known as the GMDN, will help regulatory bodies and manufacturers to cooperate in the exchange of regulatory information about medical devices. This project has been funded by the European Commission with a contract administered by CEN through the British Standards Institute ([BSI](#)).

The existence of a single global nomenclature for medical devices will facilitate the exchange process and help avoid confusion.

STATUS UPDATE:

At its meeting on 19-20 March 2001 the GMDN Project Council (PC) agreed that the Nomenclature was ready to be published. This decision was presented to the responsible technical committee, CEN/TC 257/SC 1 at the meeting of 21 March 2001, where also members of ISO/TC 210/WG 3 were invited. Here it was decided to recommend the Nomenclature for publication as a CEN Technical Report through the CEN procedure, and to ask the ISO committee to forward a similar proposal.

Formal publication of the Global Medical Device Nomenclature as a technical report is expected around mid July 2001. In addition to its paper format, the GMDN will also be launched as a CD-ROM containing this same data file. This will readily be available to the Competent Authorities and similar bodies together with an agreement concerning its use. More sophisticated electronic versions and other electronic applications using the GMDN data file will have to follow as demand for its availability increases.

The first version of the GMDN contains a total of 15 936 terms. Just over 9800 of these are derived from existing nomenclatures and about 6100 are new and have been developed in absence of suitable existing terms. Out of the total number 6259 are so called preferred terms. Each preferred term is supported by a definition and are the terms by which medical devices may be classified. In addition, the nomenclature is supported by 700 template terms and a further

8977 synonym terms that act as navigational terms.

The next stage of progress is the setting up the GMDN Maintenance Agency (MA). A call for tender was placed at <http://www.bsi-global.com/Technical+Information> Only a few companies, but competent, were attracted the first time. A new call for tender will therefore go ahead this summer and interest should be expressed to gmdn@bsi-global.com

Establishing the Policy Group (PG) will take place at a joint meeting with the PC on 19-20 July this summer. Nomination of the candidates for the PG is in progress and a take over of responsibilities will soon be possible.

It is the intention to provide regular updates on the GMDN status and that this information can be freely distributed.

THE ADVANTAGES GAINED BY USING A COMMON CLASSIFICATION AND NOMENCLATURE FOR MEDICAL DEVICES

By Jacob Nordan (NKKN), Richard Moore (EUCOMED) and Masaaki Naito (JFMDA) – members of GMDN Project Council

Following recent work by the standards organisations CEN and ISO we now have a standard as a basis for building a nomenclature for medical devices. This standard is published as EN ISO 15225 *Nomenclature – Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange*. Following this a project was set up by CEN with financial support from the European Commission. The aim was to create a comprehensive nomenclature for all medical devices suitable for use by all interested parties globally. This nomenclature is named GMDN (Global Medical Device Nomenclature).

The GMDN is now about to be launched. The project is managed by Robert Allen of the UK Medical Devices Agency (MDA) and the secretariat is with British Standards Institute (BSI). For three years some 70 people have been actively involved in its development, notably from Europe, Japan and USA. Based on a recognised standard and with a broad representation in its Project Council (PC), its Expert Advisory Team (EAT) as well as in its Device Expert Task Groups (DETGs) it is foreseen that the finalised GMDN will be accepted by everybody having an interest in rectifying the unacceptable lack of a global nomenclature system that exists today.

Why this Nomenclature?

Within all regulations concerned with medical devices there are first of all a number of obligations placed on the manufacturer. We have the authorities faced with the task of regulating manufacturers and their devices, and there are people involved in trade with these devices, e.g., suppliers, before the devices themselves are finally brought into use. And, of course, there are the users. This means that we have a number of players with quite different responsibilities but all with the common interest of ensuring the availability of sound medical devices. To assist this important process there is a need for a common method for describing and identifying the device in question in an unambiguous manner.

Prior to the GMDN, many nomenclature systems existed which have been built upon different structures, and which have been used locally or nationally for different purposes. These different systems, though often workable in their own right, have no impact in improving the overall situation of providing a common platform whereby medical devices can be correctly identified and related data safely exchanged. The advent of the European directives have initiated a new era where national, and indeed international bodies, are given the opportunity to co-operate and harmonise efforts to achieve something that they all need. Furthermore, running and applying different nomenclatures world wide, is extremely time consuming and expensive without improving the data quality to the level required by modern data communication.

Manufacture

So let us start with the manufacturer. Whatever regulations exist, the manufacturer will have to go through some kind of procedure before the device is allowed on the market. This will normally be a conformity assessment according to agreed criteria, for high risk devices by a third party like a Conformity Assessment Body (CAB) or as an approval in more traditional regulations. In most cases this will lead up to a registration of the device with some authorities. It should be obvious

that a standardised, well formulated generic description of the device, together with an appropriate term name, i.e. what people involved in that particular discipline would recognise as a sensible term ordered in a nomenclature hierarchy, will facilitate communication. There would then be little dispute about what the manufacturer claims has been produced. For those involved in the assessment process access to reference literature and to standards would be better and certificates issued will be less ambiguous. In contrast to the methods applied today, where the user (hospitals), or the authorities, are individually making qualified classification attempts of the products they are selectively interested in, resulting in the proliferation of mass ambiguity, a classification done at the start of the process will be the only sensible solution.

Registration

With a comprehensive nomenclature, authorities receiving the registration will have a much greater opportunity to build up a database useable for their coming tasks. In order to make registration an activity useful for the future, and not simply another useless burden, a proper generic description of the involved device, together with its make and model, is essential. The nomenclature must be comprehensive and cover all the devices put on the market or considered a device at a global level, and give a definition suitable for a correct classification of the device in question.

Incident reporting

In the post marketing phase feedback from the users will be an all important key factor for any vigilance system. Through incident reporting schemes, information will be collected and reacted upon. Manufacturers, authorities and users will potentially be involved. Unambiguous classification of the involved device, giving a proper, generic description is essential for the communication necessary in the follow-up. Without it statistics and trend analysis is at best difficult, usually impossible.

Trading

For trading purposes, and in particular with tendering procedures, the generic definition given in the GMDN will be useful. Together with a possible specification, or with defined attributes, necessary data for the device itself is provided. With electronic trading these advantages should be obvious for involved persons on both sides of the table. The new GMDN will again provide a basic common platform, which is necessary if electronic trading is to become a reality and not just local experiments.

Inventory, stock keeping and life cycle

For the bigger purchasers, notably hospitals, keeping track of devices and knowing what is in stock is a major task. For consumables it is in many ways a matter of preparedness, for capital goods it will also concern maintenance and use records.

Who should classify?

To assign a medical device its correct classification, i.e. its predefined definition and linked term is not an easy task. Even among people trained by the same instructor there will be different views and hence a different classification. The only secure way to have a device classified is by its manufacturer who will know its intended purpose and the way it is intended to operate and perform, as well as the technology involved. This operation will make certain everybody later involved, be it in assessment, registration, trade, purchase or incident reporting knows its proper classification (i.e. the term and definition).

What does the GMDN look like?

Device Category (1-12)	The Generic Device Groups are placed into 12 Categories. This categorisation is done partly for administrative purposes, e.g. dentists can select their part of the nomenclature covering their products, but the Category may also indicate the manufacturer's intended purpose.
	The GMDN's main content is a generic definition and a term suitable for each group of devices having a number of

Generic Device Group with Code	properties in common. In fact, devices within one Generic Device Group will normally be used for the same medical purpose. These Groups, at present numbering some 7.000, each have their own unique code assigned. This code is a consecutive five digit number containing no information in itself, it is used for data transfer and communication purposes only.
Device Type Manufacturer's Label: Make & Model GMDN Code	Below the level of generic Device Group the manufacturer operates with his Device Type identification. This is the level where the manufacturer assigns the product its actual name. This is the place for the make and model and any other accompanying information, e.g. serial number, trade name, etc.

Maintenance and further improvement

The future responsibility for the GMDN will be placed with a Maintenance Agency (MA) consisting of a Policy Group (PG) and a Secretariat (MAS). The PG will have a maximum of 14 named persons with an even global representation from the main stakeholders, notably industry and authorities. A secretariat will be chosen among suitable candidates through a tendering procedure and must have a sound basis for running such an activity, including specific competence within this field.

The GMDN will not be perfect when first launched. It will have to be looked at and tried, and experience gained in order to come closer to an optimal nomenclature. Through procedures set up by the PC and the PG a well functioning feedback system will be there to secure the necessary corrections, improvements and its further development.

Conclusions

All parties involved with medical devices; be it manufacturers, regulators, conformity assessment bodies, traders, owners or users will all have a common interest in an unambiguous classification, i.e. definition and term, with each device. The obvious person to assign a device to its class is the manufacturer. By using the GMDN all players will have at hand a globally recognised tool providing better results for all. JWN2001.06.07

GMDN AVAILABILITY

The new global device nomenclature is the copyright property of CEN and will be issued as an electronic file as well as a technical report. It is anticipated that the GMDN will be cleared for release by June 2001 and that the electronic version on a CD-ROM will be the accepted form. For those who need it urgently, a request may be submitted to the project manager, Mr. Robert Allen of the MDA, UK where a version accompanied with a letter of copyright and commitment could be supplied to companies, organizations, and persons of repute.

THE USERS

The primary users and applications for the GMDN are expected to include the following:

Medical device manufacturers

- Product registration with public authorities.
- Tracking complaints and liaison with regulatory bodies.
- Responding to tenders from healthcare agencies.

Regulatory and conformity assessment bodies

- Product registration required by regulations.
- Post-market surveillance data collection and analysis.
- Information relating to death/serious injury incidents exchanged between countries and trade blocs.
- Information exchange on conformity assessments carried out under Mutual Recognition Agreements.
- Conformity assessment certification awarded to manufacturers.
- Safety and performance warnings and advice issued to medical device users and patients.

Healthcare agencies

- Specification of devices for purchasing.
- Medical device stock control systems.
- Asset registers (a regulatory requirement in some countries).
- Service and maintenance registers.

Suppliers of data management systems

- Standard up to date listing of all medical devices for integration into commercial systems supplied to manufacturers and healthcare agencies.

MAINTENANCE AGENCY (MA)

PROPOSALS FOR THE RULES OF PROCEDURE FOR THE GMDN MAINTENANCE AGENCY.

(Source document: CEN/TC 257/SC 1 N 131 from 4. January 2000)

A maintenance Agency (MA) has been proposed to ensure that the GMDN project is kept up to date after the project is completed and closed down. It is intended to be "global" (international) and that the lead is to be taken by CEN.

The experience of developers' of existing nomenclatures indicates that the GMDN will need to be updated at frequent intervals (e.g. every 3-4 months) particularly as it initially comes into widespread international use. In addition, changes to the GMDN will be needed as new medical devices are developed and placed on the market, new applications found for existing devices and old device technologies become obsolete. Information about updating of the data will be issued as a newsletter.

In resolution BT 146/1994, the CEN/Technical Board approved the guidelines for the MA. These guidelines are also taken up in the CEN System Handbook (chapter MAINT/MA)

It is proposed that when completed the GMDN will be prepared as a CEN/ISO Technical Report titled "Global Medical Device Nomenclature" available as a document in the normal way. Separately, the nomenclature terms, definitions, codes and related data contained in the Technical Report will be marketed as an electronic database file that can be directly imported into the databases of users.

PROPOSAL – ESTABLISH A MAINTENANCE AGENCY TO MAINTAIN THE GMDN

It is proposed that:

- a) the Technical Report will be developed in parallel with ISO (Vienna Agreement, CEN-Lead);
- b) the Technical Report will be maintained through a Maintenance Agency (MA) set up under CEN and ISO but with the lead through CEN;
- c) the MA to be supported by a Secretariat body, under contract to CEN, responsible for all administrative matters, publication of the Technical Report newsletter and marketing of the Technical Report data as an electronic file.

ROLE OF THE MAINTENANCE AGENCY

In developing the Technical Report, hereafter referred to as the GMDN, consideration was given to its maintenance by use of a MA.

As for the GMDN, the MA is intended to be "global" (international), and the lead of it is to be taken by CEN.

The MA will have the following responsibilities:

- a) to ensure that internationally, the GMDN meets the needs of the regulatory bodies, industry and other users as the primary reference and working nomenclature for the exchange of regulatory information;
- b) to ensure that the GMDN is constructed in compliance with the standard, EN ISO 15225, and any guidance issued by CEN/TC 257/SC 1 working in collaboration with ISO/TC 210/WG 3;
- c) to be responsible for adding, amending and archiving terms and definitions for medical devices and to assign codes as required in accordance with the specification in the standard, EN ISO 15225;
- d) to liaise with CEN/TC 257/SC 1 and ISO/TC 210 WG 3 to provide feedback on the application of the GMDN and ensure that the standard, EN ISO 15225, is kept up to date and meets user needs;
- e) to establish and co-ordinate with appropriate organizations translations of the GMDN into other languages to facilitate its international use.

MAINTENANCE AGENCY MEMBERSHIP

The MA to consist of:

MA Policy Group: a maximum of 14 named members each appointed for a period of 5 years.

Up to 10 of the members to be nominated from within CEN and/or ISO to encompass manufacturers' and device users' interests. The following regulatory bodies to be invited to each nominate one representative to the MA Policy Group, participation being voluntary.

Global Harmonization Task Force

European Commission, DG III (Europe)

Food and Drug Administration (USA)

Ministry of Health and Welfare (Japan)

At the proposal of the Secretary-General of CEN, other CEN and ISO member bodies organizations with special expertise in nomenclature and international organizations may be associated with the work of the MA. The associated organizations may each appoint one representative member. The associated member has the same status as the other members but does not participate in voting.

Ideally the MA Policy Group should have a balanced membership representative of regulatory agencies, manufacturers and medical device users

MA Experts: up to 8 named medical device nomenclature experts from organizations selected by the MA Policy Group, including

ECRI
FDA
NKKN

The MA Experts may co-opt additional medical device experts as required to assist in the development/amendment of terms and definitions.

RESPONSIBILITIES

Maintenance Agency Members

The MA shall be responsible for all functions listed in the "role of the maintenance agency" and ensuring that the procedures for maintaining the GMDN are carried out in a timely manner. The MA shall respond and comment without delay within specified time limits on MA matters and nominated members attend meetings of the MA, as required.

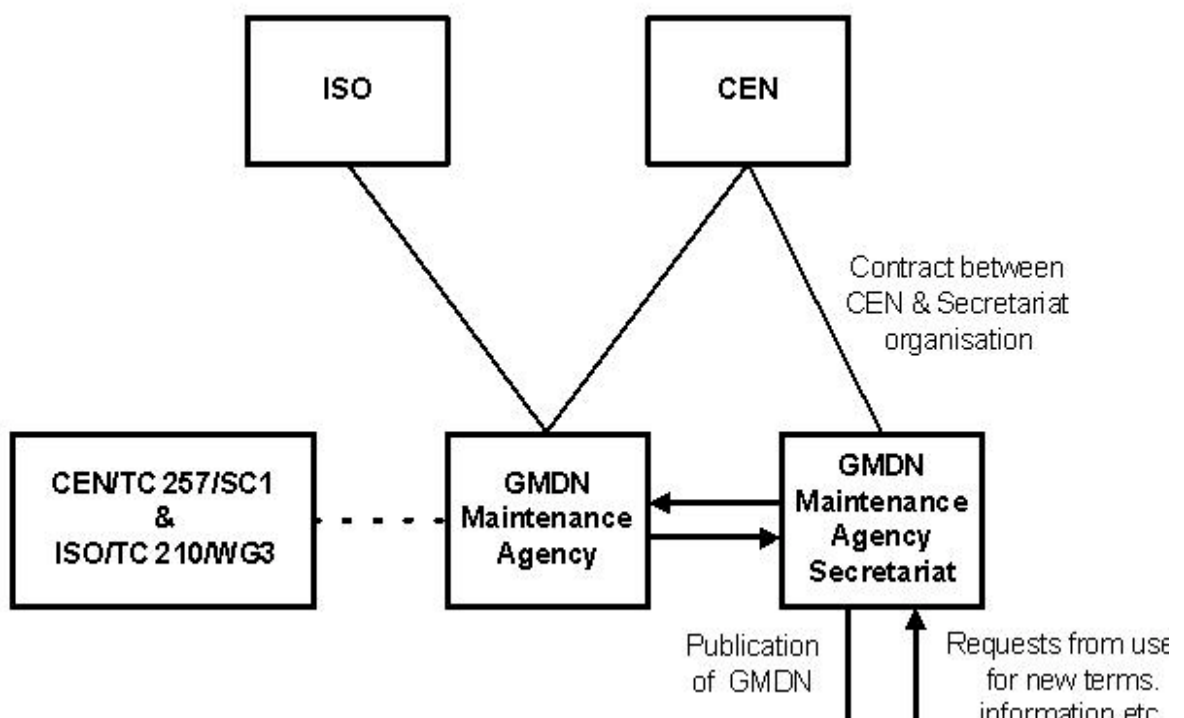
MAINTENANCE AGENCY SECRETARIAT (MAS)

The MA is to be supported by a secretariat (MAS), as designated by the CEN/Technical Board.

The MAS is responsible for the administration of maintenance procedures, including voting; preparation of material for external contacts to be executed by the Secretary General of CEN; publication and dissemination of results of the maintenance procedures. The MAS is also responsible for:

- a) maintenance and publication of the GMDN at appropriate intervals so that the GMDN is maintained in an up to date form;
- b) receiving all proposals for changes to the GMDN;
- c) advising users regarding the application of the GMDN by means of the Newsletter;
- d) maintaining an efficient communication and documentation to MA members and other interested parties;
- e) making agreements, in consultation with CEN/CS and the ISO/CS for non-CEN countries, with other bodies so that they may create translations of the GMDN into other languages. Such agreements to include obligations on the other bodies to ensure that codes assigned to terms in the English version are retained in the other language versions. The bodies to be responsible for publishing and distributing the other language versions and ensuring that they are maintained, unless alternative arrangements are agreed with the MA;
- f) arranging for publicity and other information about the GMDN as appropriate.

Diagram to illustrate relationship between the bodies involved in GMDN Maintenance Agency



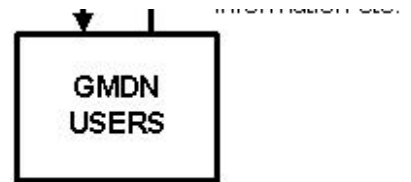


Diagram to illustrate the organization of the GMDN Maintenance Agency

