

The advantages gained by using a common classification and nomenclature for medical devices

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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.

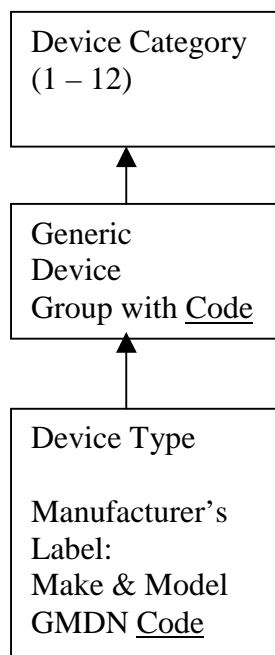
Inventory, stock keeping and life cycle

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?



The GMDN's main content is a generic definition and a term suitable for each group of devices having a number of 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.

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.

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.

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