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Global Medical Device Nomenclature: Basic concept and Five-Year strategy

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Abstract

Many people are involved in the medical device industry and their motto is to ensure the safety of medical devices, while having very varied roles and levels of process knowledge. For the first time, Global Medical Devices Nomenclature (GMDN) enables an international system to identify all medical devices generically. The GMDN now enables, for the first time, an international system for generically identifying all medical devices in a helpful way to all users. Many nomenclature systems were in existence before the GMDN, all of which were based on various structures and had been used locally or nationally for unique objectives using different techniques. In this article we are explaining the basic concept of GMDN, importance of naming, the need of GMDN, global acceptance. GMDN term structure involves finding codes and searching for GMDN terms. In addition, there will be an explanation of the Unique Device Identification (UDI) and UDI requirements carrier & hardware relationship between UDI and GMDN. Finally, the five-year strategy (2022-2026) focuses and sets out an ambitious vision for growth and increased global harmonization. The strategies set out in specific programs of work that will drive development in the coming years are also mentioned.

Keywords: Medical devices, Nomenclature, Global medical device nomenclature, Unique Device Identification, five-year strategy

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1. Introduction

According to the World Health Organization (WHO), Any device, instrument, machine, appliance, implant, reagent for in vitro use, software, material, or other similar item intended by the maker to be used, either alone or in combination, for a medical purpose is considered a medical device. Some of the medical devices are Single use devices (like syringes, catheters), Implantable (like prosthesis, pacemakers), Imaging (like CT scanners and ultrasound), Surgical and laboratory instruments, *in vitro* diagnostics (like HIV tests, glucometer), medical equipment (like anaesthesia machines, patient monitors), Software (like computer aided diagnostics) and personal protective equipment (like masks, gowns and gloves). (1) The Nomenclature is a naming system for products which are used in the diagnosis, prevention, monitoring and treatment of injury/disease. These naming conventions satisfies a range of needs, including those for stock management, regulatory compliance, adverse event reporting, and accounting in addition to maintenance, procurement, and accounting. The recording and reporting of medical devices is done using a standard nomenclature for medical devices. The National Classification of Medical Devices (CND), the European Medical Device Nomenclature (EMDN), the Global Medical Device Nomenclature (GMDN), the Universal Medical Device Nomenclature System (UMDNS), and the Unique Device Identifier are some of the most significant nomenclatures and identifiers currently in use (UDI).

Global Medical Devices Nomenclature (GMDN) was established in 1991 and is a system of generic description used to identify all medical device products which is agreed internationally with the purpose of providing conformity to assessment bodies, health regulators, health care providers and others with a single generic naming system. According to different classification and nomenclature systems, there are between 5000 to 24000 different types to medical devices. They range from the very simple to complex, from expensive to costly. The number and types of devices are increasing exponentially. GMDN is based on the International Standard of (ISO) 15225. ISO started to work on a global standard nomenclature for medical devices in 1996. It is used over 70 national medical devices. There are 22,000 preferred terms with definition

and free access to all GMDN terms made available following a request from WHO and EC in 2019. In 2008, GMDN was started to be translated into multiple languages. (2) The milestones of GMDN were given in Figure 1. (3)

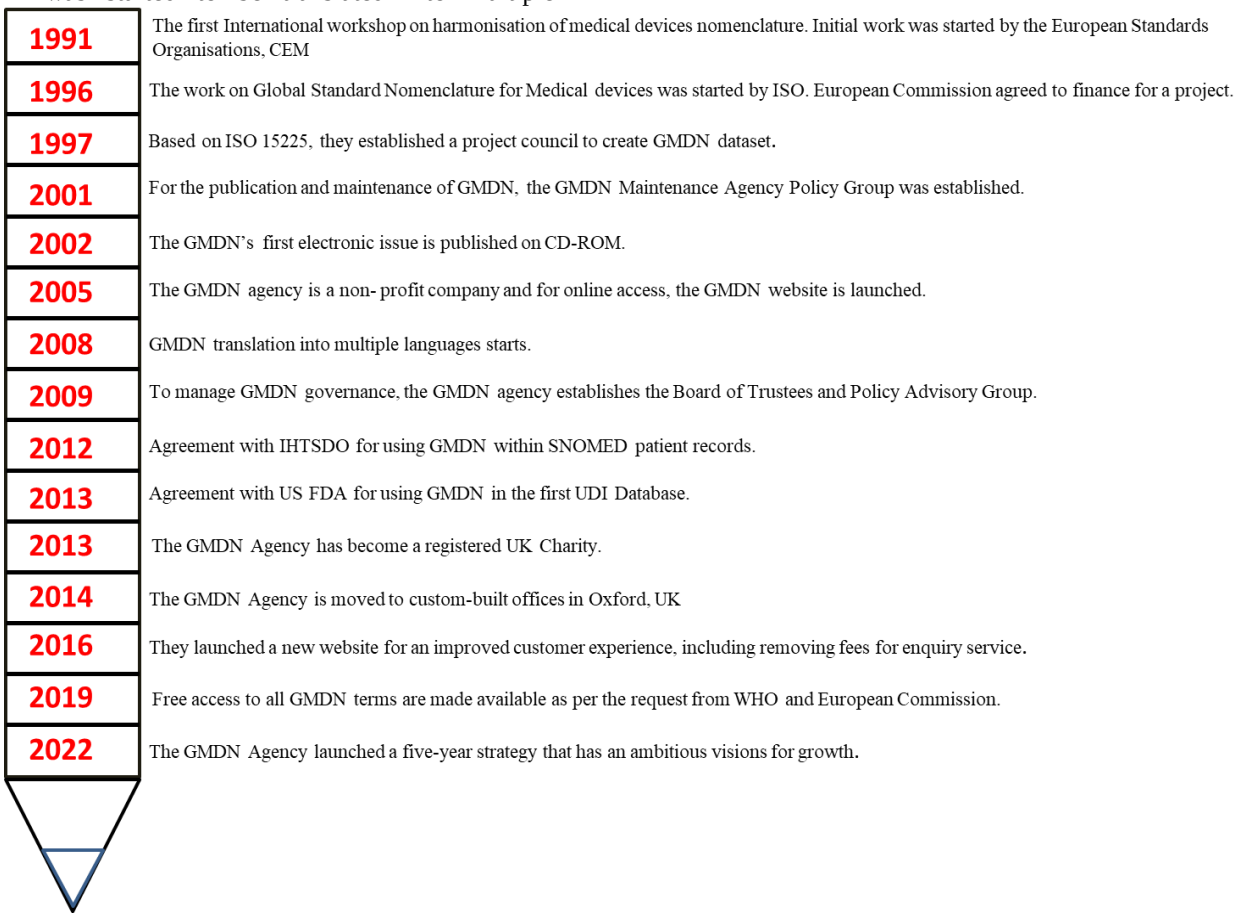

Figure 1. Milestones of GMDN

2. Naming of GMDN & Global Acceptance

Naming is important to trade and identify medical devices internationally. By identifying product categories, associated problems, and systemic failures of medical devices, regulators can quickly approve devices. By identifying product categories, associated problems, and systemic failures of medical devices, regulators can quickly approve devices. It supports hospitals in maintaining their inventories and determining which supplies they require. The authorities are provided a unique global nomenclature system by GMDN to regulate medical devices. This shows an impact on healthcare providers who are the primary users of medical devices as well as suppliers, manufacturers and conformity assessment bodies and other related parties. The GMDN code is a general description for the purposes of post-marketing vigilance exchange, research, medical record keeping, e-commerce, inventory, and safe information sharing between competent authorities and others. (4,5) The global acceptance of GMDN include,

- Global Harmonization Task Force (GHTF) helps to accelerate GMDN. Now the GHTF has been replaced by the International Medical Device Regulators Forum (IMDRF) in 2012.
- The European Association of Medical Devices (EUCOMED) encourages the use of GMDN to meet the requirements of European manufacturers
- WHO and Doctors Without Borders (Medicines' Sans Frontières) use the GMDN guidelines for developing countries
- US FDA use of GMDN is the first national implementation of Unique Device Identification (UDI)

At present six selected nomenclatures were used to represent medical devices in various countries. They are:

The US FDA developed Classification Names for Medical Devices (CNMD) and *In vitro* diagnostic products.

- European Diagnostic Manufacturers Association (EDMA) manufactures *In vitro* diagnostic products in Europe.
- Technical aids which come under ISO 9999 are used internationally for persons with disabilities.
- Japanese Federation of Medical Devices Association (JFMDA).
- Norwegian Classification, Coding & Nomenclature (NKKN), Norway.
- ECRI, USA developed the Universal Medical Device Nomenclature System (UMDNS).

3. Structure, Finding of GMDN Codes and Terms:

The term GMDN is placed in the form of a 5-digit code cross-referenced to a specific name and term definition that can be used to identify all medical devices that have essentially similar generic characteristics. Each GMDN term has a set of attributes which are known as collective conditions which enables it to navigate the GMDN database and assist in selecting a GMDN term based on a health condition or product characteristic. Each GMDN term consists of 3 parts:

- **Term Name:** General Purpose Syringe
- **Definition:** A calibrated hollow cylinder and a moveable plunger help compensate for a sterile device that is used to inject fluids into the body or operate other medical equipment.
- **Code:** 47017

The GMDN Agency updates GMDN by receiving requests to add new generic facility terms, remove current terms, or alter names or term definitions. A worldwide advisory group makes decisions in line with ISO 15225. Daily GMDN updates are posted on this agency's interactive GMDN Database website. Only members like conformity assessment bodies, regulators and health care providers can access the GMDN database. From April 1, 2019 GMDN incorporated membership and thus it provides estimation to GMDN terms and conditions and codes charge less. GMDN is accessible in English and other languages. (6) The official website was launched in 2005, www.gmdn agency.organisation. To find GMDN, you need to log in to the GMDN account and search for the data required based on the instructions on the screen as depicted in Figure 2. It is a non-profit organization responsible for creating and maintaining GMDN terms and conditions, to get the data from the site needed to register, the process is given in Figure 3.The term GMDN is assigned by the manufacturer for regulatory bodies and hospitals worldwide. It can be used in the following way;

- Identify the GMDN code for all your products from the GMDN database
- Provide the GMDN code to your customers / distributors / data pools
- Use the GMDN code to register your products with your MD regulator
- Use Unique Device Identification (UDI)

Unique Device Identification - UDI is a special alphanumeric or numeric code that typically includes

a) Device Identifier (DI): It is the obligation, fixed which identifies the labeler and the particular version or model of the device, is part of the Universal Device Identification (UDI).

b) Production Identifier (PI), a conditional, variable portion of a UDI that, when shown on a device label, designates one or more of the following:

- The manufacturing lot or lot number for the device.
- The device's unique serial number
- The expiration date of a specific device
- Date of manufacture of a specific device;
- The unique identifying code needed by section 1271.290(c) for any human cells, tissues, or cell and tissue products (HCT/P) classified as medical devices.

Figure 2. Official website of GMDN

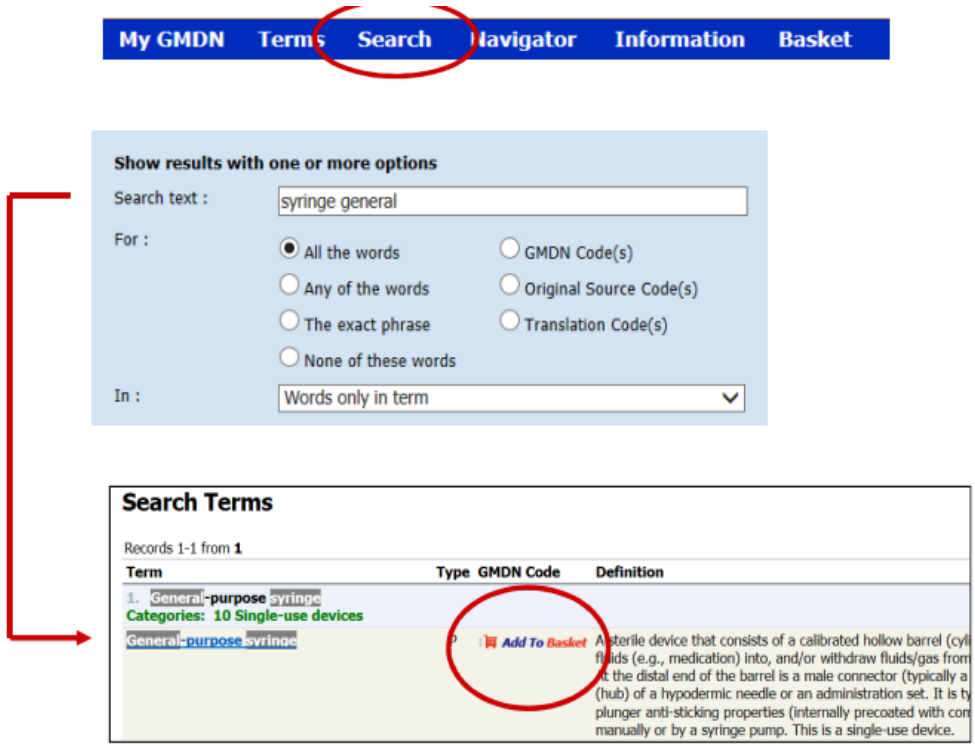

Figure 3. Searching process in GMDN site

UDI on labels and packaging should exhibit two properties, easy to read plain text and a machine-readable form that uses automatic identification and data collection (AIDC) technology. It is any technology that transmits a device's UDI or device identifier in a way that can be automatically entered into an electronic medical record or another computer system. In accordance with international standards and best practices, the device labeller must also give information on device labels and packaging in a consistent format (YYYY-MM-DD), sample UDI was depicted in Figure 4. To read the UDI a carrier and hardware is required. The UDI carrier may be a 2D barcode or linear barcode or Radio Frequency Identification (RFID). The hardware used to read are barcode reader, image scanner and RFID scanner, they are depicted in Figure 5.

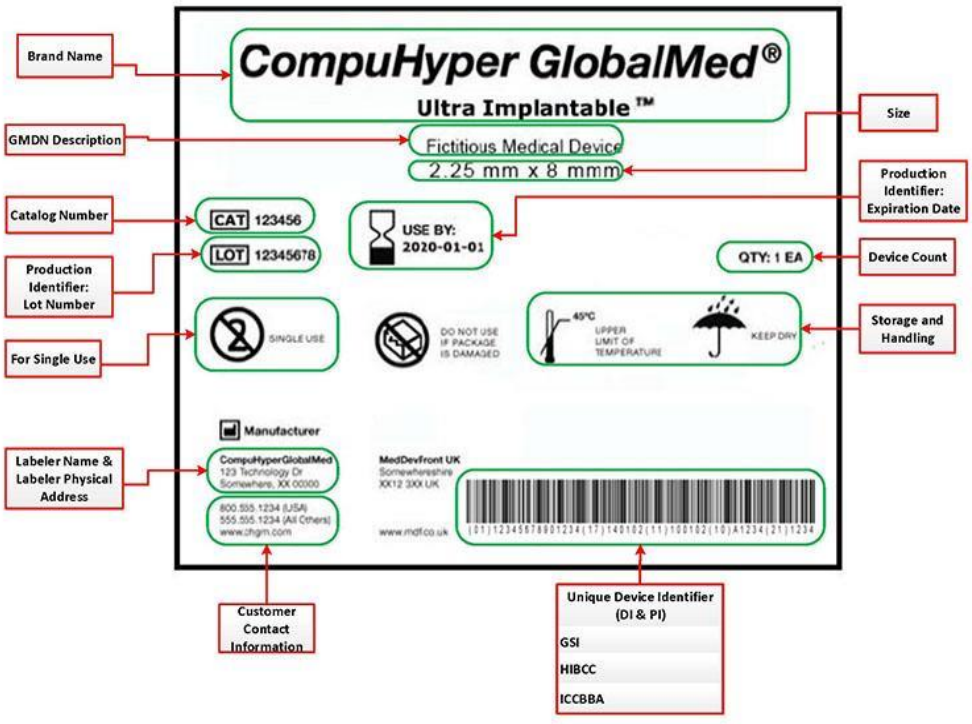

Figure 4. Sample UDI

a)

b)

Figure 5. Image of a) UDI carrier b) reader

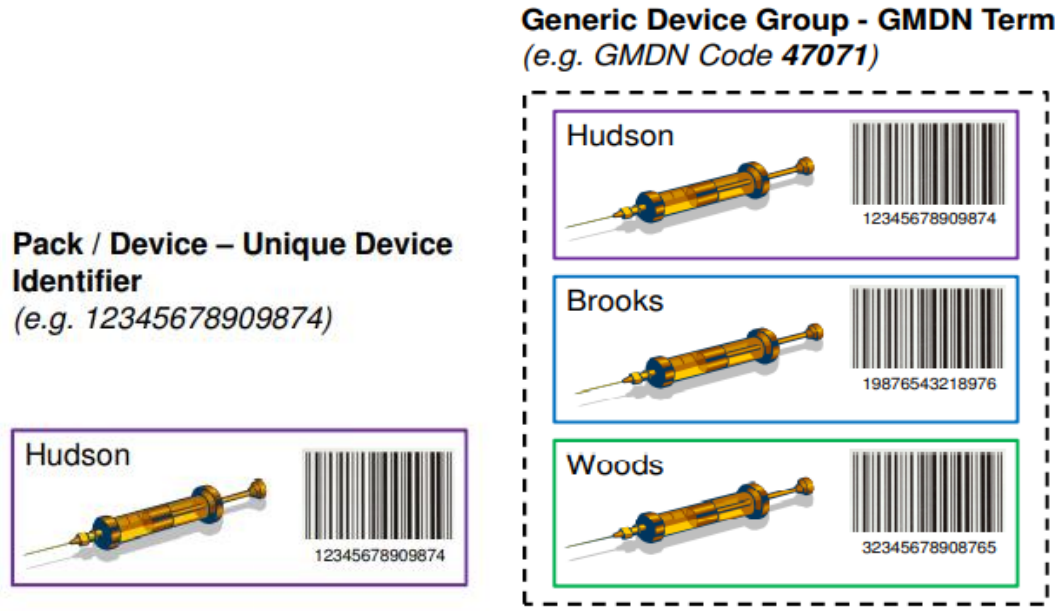

Figure 6. Difference of UDI and GMDN

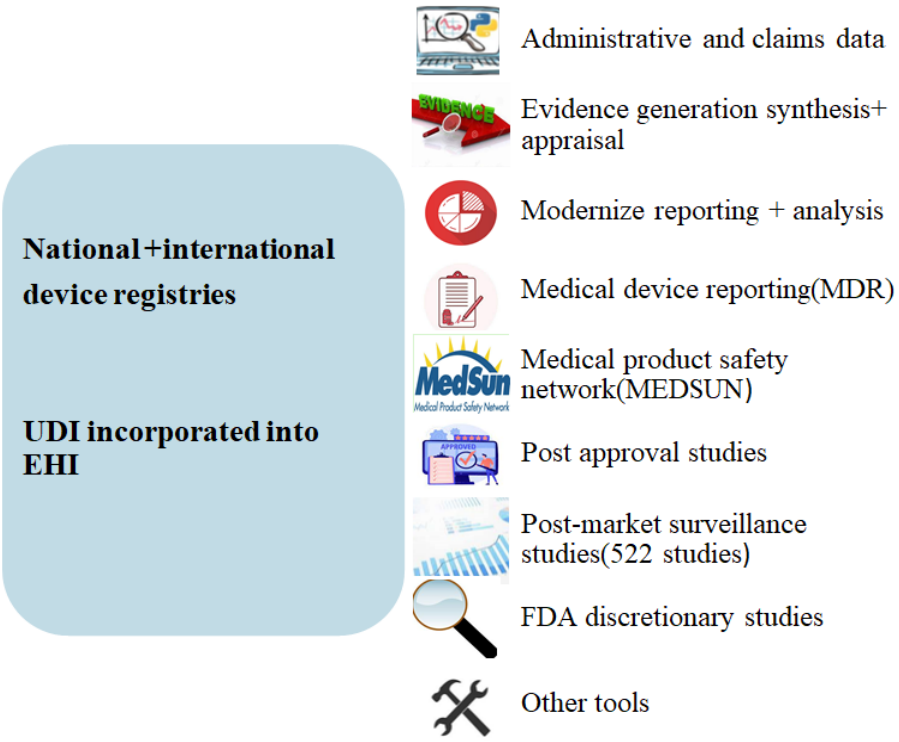

Figure7. Post Marketing Surveillance

A single UDI identifies one particular device from one manufacturer. GMDN code identifies a group of devices with identical characteristics from different manufacturers as shown in Figure 6. They require better regulation by speeding up premarket approvals, quick identification of products, quick identification of new device usage trends and detailed information on imports and exports. (7,8)

Post Marketing Surveillance

A post-market monitoring system can also be used to approve new and already-marketed products before they are put on the market. No matter how many times the equipment is repackaged or relabeled, stakeholders (such as manufacturers, distributors, and healthcare facilities) should be given a consistent identity to manage recalls effectively figure 7. (9)

4. Five year strategy of GMDN (2022-2026)

The GMDN agency introduced a five-year plan which has set its goals for the development and increased global harmonization. The method significantly changes to support the creation and application of nomenclature in a wide range of applications. The vision of GMDN is to provide universal language for medical technology for easy access by the stakeholders. The steps involved in GMDN nomenclature development are depicted in Figure 6. The team members developed four ambitions viz., promote the value of global collaboration and harmonization, continuously improve and innovate, provide excellent services which add value, be engaged, helpful and expert at the end of the five-year strategic period. The framework defines five distinct work programmes that will direct its development over the next few years.

They are:

- *New legacy transition tools*: By providing a service to assist users in changing from their legacy nomenclature and converting their existing data to use GMDN terms.
- *A Bespoke device grouping service*: According to this, Users will be able to establish unique sets of GMDN conditions for a particular purpose.
- *Term Assignment Support programme*: Implementation of a monitoring strategy to spot GMDN/ product assignment faults and advise the members of it.
- *Stakeholder Outreach*: Establishing a programme to find stakeholder groups that can help the GMDN'S development, utility and effectiveness.
- *Harmonization support*: The development of tools to aid international collaboration, including the exchange of real-world evidence of device effectiveness, resources to aid in the assessment of new technology, and resources to track the long-term safety of devices. (10)

5. Conclusion

Global Medical Device Nomenclature provides a comprehensive and unambiguous coding system to describe medical devices for the purposes of regulatory approval. Better exchange of information between competent authorities like healthcare providers, academics, and the third sector and they all are using the nomenclature more frequently, according to the GMDN Agency. Additionally, regulators hold the information in

the same way as defined, patient safety is improved. In an era of increasing applications of data science, harmonizing critical elements of multiple data sets will be one of the keys to improve public health.

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Conflict of Interest

The authors declared that they have no competing interests.

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