GHWP/WG9/P001/2026

GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

# PROPOSED DOCUMENT

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| **Authoring Group:** | Work Group 9 – UDI and Nomenclature |
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# 1. Nomenclature Research Achievements of the Global Harmonization Working Party (GHWP)

The early involvement of GHWP in nomenclature-related work can date back to 2005. At the 10th GHWP Regional Meeting held in Malaysia on November 24 to 25, 2005, definition, classification, and universal nomenclature system were explicitly identified as priority areas for harmonization and included in GHWP's 2005-2007 work plan.

At the 12th GHWP Meeting held in Chengdu, China, in 2007, it was resolved that Asian Harmonization Working Party (AHWP) would collaborate closely with the Global Harmonization Task Force (GHTF) to address issues related to the Global Medical Device Nomenclature (GMDN) database. In 2008, the GHWP Nomenclature Task Force worked with GHTF to resolve challenges in unifying a global nomenclature system.

On October 18, 2015, GHWP released the *Guidance for Medical Device Nomenclature Rules*. This document outlines the purpose, principles, scope of application, structure and composition, and prohibited content for medical device nomenclature rules. It applies to all products meeting the definition of medical devices, excluding *in vitro* diagnostic (IVD) reagents regulated as medical devices. The Guidance primarily references the *Rules for Medical Device Nomenclature* (Decree No.19, 2015) issued by National Medical Products Administration (NMPA), while definitions of medical devices mainly draw from two guidance documents of the GHTF Study Group 1: "GHTF-SG1 N071:2012" and "GHTF-SG1 N70:2011".

## 2. Current International Nomenclature

### 2.1 Global Medical Device Nomenclature (GMDN) system

#### 2.1.1 General

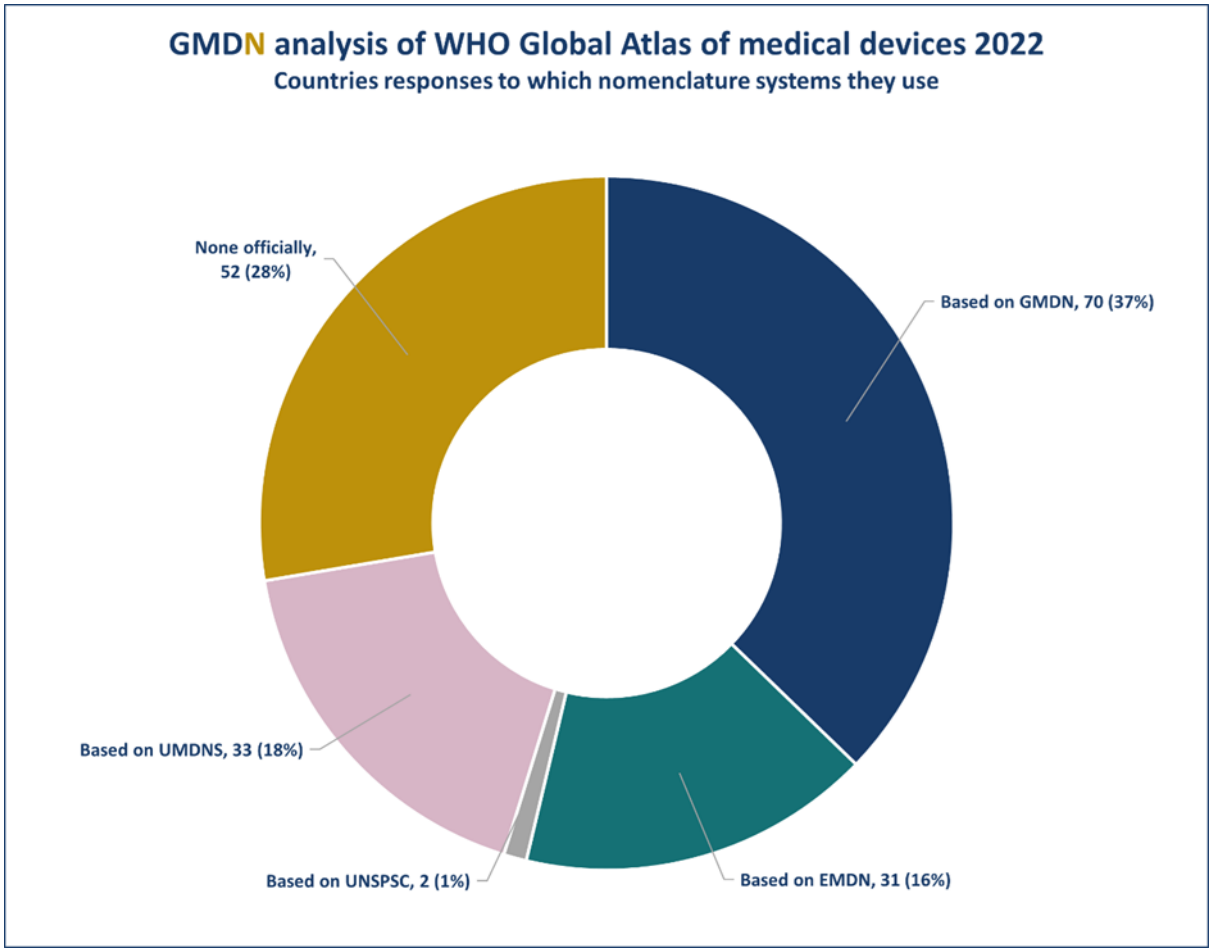
The first GMDN dataset was created in 1997 in response to a need for an international standard nomenclature for medical devices; the initial work was started by the European Standards Organisation CEN and later supported by the GHFT, which is now known as IMDRF. It is managed and maintained by the UK-based non-profit charity, the GMDN Agency. GMDN provides regulatory authorities, healthcare institutions, medical device manufacturers and distributors, conformity assessment bodies, and other stakeholders with a unified language for identifying medical devices.

In 2024, the World Health Organization (WHO) and the Global Medical Device Nomenclature (GMDN) Agency began a collaboration that saw the WHO using 3,000 GMDN Terms, Codes and Definitions within its online medical device information platforms such as the MeDevIS (Priority Medical Devices Information System), an open access WHO electronic database of Medical Devices.

UNICEF also have full access to the GMDN Database and dataset which they use within the UNICEF catalogue and published tenders.

At present, countries including United Kingdom, Australia, Brazil, Colombia, Ethiopia , Canada, and others require GMDN as mandatory or as required data but not mandatory.

According to the analysis of the WHO Global Atlas of Medical Devices 2022 done by GMDN:




### 2.1.2 Structure

The GMDN is a nomenclature in a multi-hierarchical classification system, consisting of

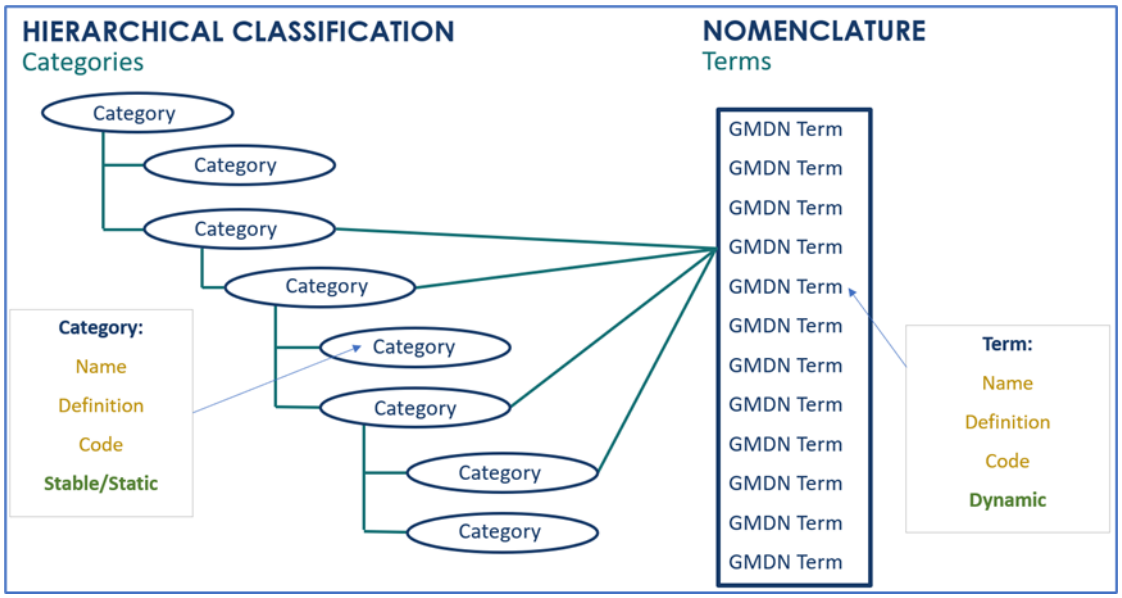
- ~ 25,000 Nomenclature Terms

Mutually exclusive, unambiguous device type descriptors (meaning no “others” or “various” categorisation) – this is the entity which is assigned by the manufacturer to each of their medical device products.

- 2,600 Categories arranged in a multi-hierarchical structure

The Categories are grouped under different headers (e.g., Device Function, Anatomical Specialty, Use Frequency, etc.). Under “Device Function”, e.g. there are 22 first-level (highest level) Categories. This provides a versatile tool for device analysis.

It is an adaptable nomenclature which can serve as a basis for higher and lower granularity as needed.




Example Term:

GMDN Code: 58301

GMDN Term Name: Synthetic polymer semi-permeable film dressing, adhesive

GMDN Term Definition: A transparent, semi-permeable (i.e., impermeable to fluids, permeable to vapours and gases) covering applied to wounded or diseased tissue intended

to provide protection (e.g., from dirt, water) and/or promote healing. It is a thin, clear film made of synthetic polymer material that is covered on one side with a pressure-sensitive adhesive. It may be applied directly to tissue or used in combination with other dressings (e.g., gauze) to protect postsurgical incisions and minor wounds (e.g., cuts, scrapes, burns, skin tears, blisters). It may also be used to secure to skin other devices such as vascular catheters, infusion ports, or tubing. This is a single-use device.

Term constituents:

Code - a five-digit number, sequentially allocated to new Terms, containing no built-in information.

Name – a unique descriptor close to spoken language.

Definition – full scope description including statements about intended use, technology/material, form/components and significant attributes (e.g. use frequency, power)

The above Term ‘Synthetic polymer semi-permeable film dressing, adhesive’ is linked to the following GMDN Categories:

- Device Function
  - CT1007 Tissue reparation devices
    - CT2775 Tissue dressing/stabilization devices
      - CT554 Dressings
        - CT2148 Dermal dressings
          - CT2154 Film dressings
            - CT2173 Semi-permeable film dressings
- Anatomical Specialty
  - CT775 Dermatological and soft-tissue reconstructive/cosmetic devices
    - CT2148 Dermal dressings
      - CT2154 Film dressings
        - CT2173 Semi-permeable film dressings
- Names Index
  - CT124 Dressings and associated devices
    - CT554 Dressings
      - CT2148 Dermal dressings
        - CT2154 Film dressings
          - CT2173 Semi-permeable film dressings
- Use Frequency
  - CT981 Single-use
- Power
  - CT2986 Non-active
- Featured Attributes
  - CT233 Surgical

The GMDN dataset evolves to keep up with innovation in the market. The GMDN Agency

maintains a dedicated expert team responsible for creating and maintaining naming and descriptions, with the motivation supplied by industry for their regulatory requirements, via a Term enquiry facility within the members account.

New Terms are created, existing Terms may be expanded in scope to include minor variations of intended use or technology, in which case the Terms Code remains unchanged, or Terms can be obsoleted when technological development means that an old concept needs to be divided in sub concepts.

Registered members will receive notifications of any changes to previously selected GMDN Codes.

#### 2.1.3 Search

Terms are obtained from the GMDN website after registration with the GMDN Agency. There is text and categorical search functionality with the ability to review and compare Term names and definitions before linking the Term(s) of interest to the member account.

### 2.2 European Medical Device Nomenclature (EMDN)

#### 2.2.1 General

The European Medical Device Nomenclature (EMDN) is a terminology classification system specifically intended support the registration of products by EU and international manufacturers within the EU. It is an entry requirement developing EUDAMED UDI database to support EU regulatory compliance under the requirements of MDR and IVDR. It is being developed by the European Commission, whose affiliated Medical Device Coordination Group (MDCG) is responsible for management and updating. It is funded by the European Commission.

In 2019, the European Commission announced the adoption of the Classificazione Nazionale dei Dispositivi medici (CND) used in Italy as the foundation for the future EMDN. The first version of the EMDN was released on May 4, 2021. Feedback is collected from users regarding corrections and suggestions on the Italian translations and grammatical aspects of the English version of EMDN in CND.

The key consideration for the development of EMDN was that it should be made available free of charge on a publicly-accessible website with a download facility. The update schedule is by annual release of a new version with the intention that innovative devices are covered

by an ‘others’ Term in the intervening year. Manufacturers are then required to review the entire updated EMDN classification to check whether a more accurate Term has been added.

Medical device manufacturers register their products in EUDAMED, where the EMDN code is one of required datapoints and is therefore linked to the Unique Device Identifier-Device Identifier (UDI-DI). EMDN is considered by the European Commission to be of value for medical device documentation, technical documentation, technical documentation sampling by notified bodies, post-market surveillance, vigilance, and post-market data analysis. Additionally, in the future, EMDN codes will be incorporated as part of the UDI-DI on product labels. It has been adopted by regulation across the 27 EU member states to standardize and unify nomenclature.

### 2.2.2 Structure

EMDN is a hierarchical classification system with terminology logic. Currently there are 22 medical device classification categories and over 8,000 terms, and continues to evolve to meet the needs of the regulatory use-case.

Each concept at all levels feature an "alphanumeric code + designation", so the name of the Terms acts as the definition of that group. The hierarchical levels of the tree structure progress from top to the variable-level terminal term. At each level there are Terms with a designation ‘-others’ or ‘various’ to provide a non-specific Term for assignment to products where a specific Term is not available or is inadequately defined. There are currently 1500 ‘-other’ or ‘various’ Terms.

The highest Level 1 is "Categories", which classifies products into 22 major categories based on their characteristics and attributes. Below categories lies Level 2 "Groups", followed by Level 3 "Types". Types can be selectively extended downward based on granular product classification needs, forming Level 4 to Level 7, i.e., Type (2) to Type (5). For Codes, categories are represented by single uppercase letters while all subsequent levels use two-digit Arabic numerals.

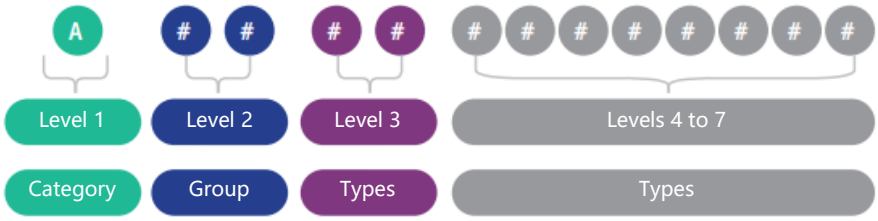



Figure 2. EMDN tree structure

The 22 categories of EMDN can be divided into 8 anatomical categories, 9 functional categories, and 5 special categories. The anatomical categories are related to the anatomical regions where medical devices are applied. Each category includes (specific) devices intended for the same anatomical region or organ, for example 'C - Cardiocirculatory System Devices' and G - Gastrointestinal Devices. Special categories consist of the remaining five categories classified according to other criteria, for example J - Active-Implantable Devices and P - Implantable Prosthetic and Osteosynthesis Devices.

### 2.2.3 Search and Use

EMDN can be accessed and downloaded free of charge on the MDCG webpage of the European Commission. The website provides the latest EMDN tree, which can be progressively expanded from the top level down to terminal level for matching and selection. The website offers fuzzy search functionality allowing users to input keywords to query EMDN codes and designations. It also supports downloading the full term list. EMDN entries provided by the website include both the Italian CND and the officially translated English versions. Currently, EMDN is continually optimizing the English designations, and EUDAMED users may directly submit feedback or suggestions on the webpage.

## 2.3 Japanese Medical Device Nomenclature (JMDN)

### 2.3.1 General

The Japanese Medical Device Nomenclature (JMDN) system was established by Japan's Ministry of Health, Labour and Welfare (MHLW), the primary governmental agency responsible for healthcare and social security. The implementation and administration of JMDN are managed by the MHLW and its database is run by the Pharmaceuticals and Medical Devices Agency (PMDA), an independent administrative agency under the MHLW.

Implemented from 2005, JMDN was established by referring to the 2003 version of GMDN, with the GMDN entries screened and eliminated. Meanwhile, to align with regulatory classification requirements, the selected categories underwent further granular subdivision. JMDN specifies product generic names, codes, definitions, corresponding management categories, and classification rule numbers compliant with the GHTF. For new or modified individual entries, regulatory authorities will publish official notices detailing changes and update the database accordingly.

JMDN database emphasizes international alignment, classification management, and scientific regulation. JMDN is mandatorily enforced in Japan. Every medical device is identified by its corresponding JMDN code. The use of JMDN is required for the registration of medical devices in Japan, and both the generic name of the device and its JMDN code must be indicated on product IFU. These elements are also associated with the UDI. Furthermore, the management classifications and related guidance information provided by JMDN assist practitioners in conducting the basic regulatory positioning of products and confirming compliance.

### 2.3.2 Working mechanism

In Japan, the regulation of pharmaceuticals and medical devices is led by the MHLW, with implementation carried out by the PMDA, an independent administrative agency under its jurisdiction. PMDA specifically handles most of medical device nomenclature-related tasks, including database maintenance, medical device classification management, and providing JMDN technical guidance to practitioners. This series of tasks aims to ensure the efficient operation of medical device nomenclature practices and the regulatory framework.

### 2.3.2 Structure

JMDN is linked to several elements such as Generic Name, Definition, JMDN Code, Classification and Classification Rules Number. Compared with the nomenclature structure of GMDN, JMDN is linked to elements such as Classification and Classification Rules Number.

Generic names, definitions, JMDN codes, classification, and classification rules. Classification Rules serve as the basis for determining medical device management categories. Japan adopts the 15 classification rules of GHTF, as shown in Figure 3. Since GHTF rules have not been adopted in Japan for IVD devices, classification rules of JMDN for IVD devices are not described.

| Classification rules number a | Overview of classification rules | Management category | Corresponding generic name quantity |
|---|---|---|---|
| 1 | Non-invasive devices other than those in Rules 2, 3, and 4 | I/II/III | 413 |
| 2 | Non-invasive devices intended to be used for channeling or storing blood, body liquids, tissues, other liquids or gases for the purpose of eventual infusion, administration or introduction into the body | I/II/III | 244 |
| 3 | Invasive devices intended for modifying the biological or chemical composition of blood, other body liquids, or other liquids, intended for infusion into the body | II/III | 74 |
| 4 | Non-invasive devices which come into contact with injured skin | I/II/III | 69 |
| 5 | Non-surgically invasive devices which come into contact with body orifices | I/II/III | 585 |
| 6 | Surgically invasive devices intended for transient use | I/II/III/IV | 762 |
| 7 | Surgically invasive devices intended for short-term use | II/III/IV | 257 |
| 8 | Implantable devices, and long-term surgically | II/III/IV | 613 |

| | | | |
|---|---|---|---|
| | invasive devices | | |
| 9 | Active therapeutic devices intended to administer or exchange energy | II/III/IV | 436 |
| 10 | Active device for diagnosis | I/II/III/IV | 647 |
| 11 | Active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body | II/III | 136 |
| 12 | Other active devices | I/II | 152 |
| 13 | Devices incorporating medicinal substances in an ancillary role | III/IV | 62 |
| 14 | Devices manufactured from or incorporating animal or human cells/tissues/derivatives thereof | III/IV | 125 |
| 15 | Devices intended specifically to be used for sterilizing or disinfecting medical devices (other than disinfectant) | II | 31 |
| No corresponding content b | / | I/II/III | 111 |

Figure 3. 15 classification rules of GHTF

The JMDN code consists of 8 digits. The first digit is 1to 7. Codes starting with 1, 3, or 4 are converted from GMDN, while those starting with 7 are unique to JMDN. Therefore, the

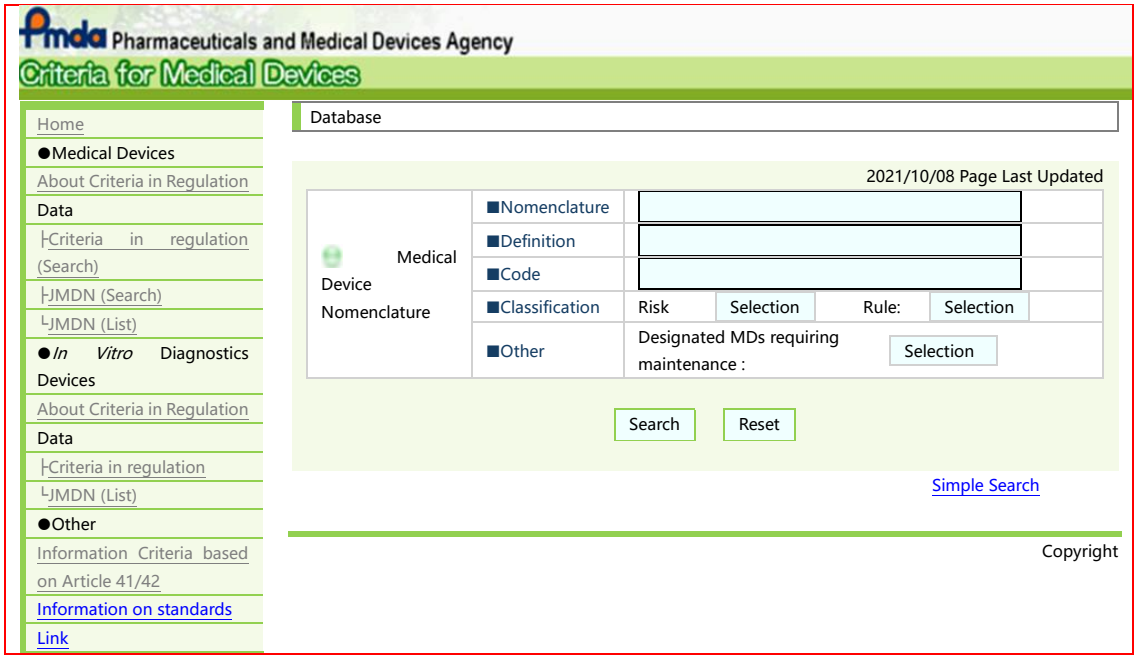
correlation between JMDN and GMDN can be identified through JMDN codes. For JMDN converted from GMDN, a 3-digit subdivision code is appended after the original 5-digit GMDN code.

### 2.3.4 Regulatory Requirement

On November 25, 2014, the Japanese government enacted the *Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices* (abbreviated as the PMD Act), under which the MHLW oversees the classification, registration, and other regulatory processes for medical devices. This legislation serves as the current legal foundation for the management and maintenance of JMDN database.

### 2.3.5 Search and Use

The PMDA official website provides free access to search and download JMDN entries. For searches, users can perform fuzzy search using product names or definitions. Advanced search options are also available by combining known details such as JMDN codes, management categories, or classification rules numbers. The website offers the latest JMDN term lists for both medical devices and *in vitro* diagnostic medical devices, which can be downloaded by users free of charge. Below is an example of the search interface and search results for code 35094:



Database

8 results found  Select Results  Display  Clear

[Key] Code : *35094*

- 1-87:Catheter guide wire for cardiac/central circulatory system
- 1-88:Heoarin-coated cardiac/central circulatory catheter guidewire
- 1-89:Central nervous system catheter guidewire
- 1-402:Vascular catheter guidewire
- 1-403:HeDarin-coated vascular catheter guidewire
- 2-832:Temoorary use catheter guidewire

| Nomenclature. etc. | Catheter guide wire for cardiac/central circulatory system<br>Class IV, Code : 35094114, Rule: 6-ⓢ |
|---|---|
| Others | Designated MDs requiring maintenance : |
| Definition | A device for adjusting the position of, or supporting the delivery of a catheter. The device is commo of coated or uncoated stainless steel, and coating facilitates its movement in the cardiovascular an vascular systems. |
| Criteria in regulation | <AC> AC47: Cardiac/Central Circulatory Catheter Guidewire criteria (2014/02/04) |
| Comment | |

Since the entry contains product management category information, JMDN can assist manufacturers in determining the management category of their products during the registration application process, thereby following the corresponding registration procedures. During registration, Market Authorization Holder must submit registration information, including the JMDN generic name and code, to ensure lawful marketing of their medical devices in Japan. Product IFU must indicate the product's generic name, JMDN code, and UDI information. The JMDN code is associated with the UDI to enable precise identification and traceability of medical devices.

### 2.4 Universal Medical Device Nomenclature System (UMDNS)

The Universal Medical Device Nomenclature System (UMDNS) was established, managed and maintained by the Emergency Care Research Institute (ECRI) in 1971. Users can access and retrieve data by registering and logging into its official website (https://www.ecri.org/solutions/umdns). As of 2025, UMDNS has included approximately 43,000 terms. This nomenclature system facilitates the identification, archiving, storage, retrieval, and transmission of medical device-related data.

UMDNS codes consist of a 5-digit numerical code and designation. Taking magnetic resonance imaging (MRI) equipment as an example:

| **UMDNS Code** | 16260 | 18108 | 18109 | 18110 |
|---|---|---|---|---|
| **UMDNS Designation** | Magnetic resonance imaging equipment | Magnetic Resonance Imaging (MRI) Units, Full-Body | Magnetic Resonance Imaging (MRI) Units, Extremity | Magnetic Resonance Imaging (MRI) Units, Mammographic |

According to the *Global Atlas of Medical Devices* published by the WHO in 2022, as of 2022, countries including Argentina, Austria, Spain, Brunei, Cuba, The Gambia, Jordan, etc. have adopted the UMDNS-based nomenclature system.

### 2.5 Medical Device Nomenclature in China

The vast variety of medical devices, coupled with their technically complex characteristics and significant structural differences, make the standardization of medical device nomenclature a critical foundational task in medical device regulation. The *Regulations for the Supervision and Administration of Medical Devices* (No.739 of the State Council of the People's Republic of China) issued on March 18, 2021 stipulates that medical devices shall adopt generic names. Generic names shall comply with the nomenclature principles for medical devices formulated by National Medical Products Administration (NMPA).

On December 21, 2015, the NMPA issued the *Rules for Medical Device Nomenclature.* The *Rules* is applicable to medical devices sold and used within the People's Republic of China, excluding *in vitro* diagnostic reagents regulated as medical devices. The nomenclature of generic names of medical devices shall comply with the Rules. The generic names of medical devices shall be in Chinese and conform to the norms of the standard spoken and written Chinese language, and shall be consistent with the actual attributes of the products. The same generic name shall apply to medical devices in the same category with the same or similar intended use and common technologies, and such generic name shall not be registered as a trademark.

The generic name of a medical device is composed of a core word and generally no more than three feature words:

-Core word refers to an overall description of medical devices with the same or similar technical principle, structure and composition or intended purpose.

-Feature word is the description of specific attributes such as application sites, structural features, technical features, or material composition.

1) The application site refers to the position where the product is used on the human body. It can be the system, organ, tissue and cell of the human body.

2) The structural feature is the description of the specific structure and appearance of the product. The technical feature is the description or limitation of the special action principles, mechanisms or special performances of the product.

3) Material composition refers to the description of main materials or major components of the product.

The *Rules* specifies the contents that shall not be contained in the generic names of medical devices:

(1) Models and specifications;

(2) Figures, symbols and other marks;

(3) Personal names, enterprise names, registered trademarks or other similar names;

(4) “Excellent” , “Only”, “Precise”, “Quick-acting” and other absolute and exclusive words, or claims or promises indicating the effect of the products;

(5) The wording of efficiency and cure rate;

(6) The conceptual names that are not verified by science or clinical assessment or the void and assumed ones;

(7) Explicit and implicit indication of curing all illness, exaggerated scope of application or other misleading and deceptive contents;

(8) Publicity words such as “Beauty” and “Health Care”;

(9) Other contents prohibited by the relevant laws and regulations.

*The Provisions for In-vitro Diagnostic Reagent Registration and Filing* revised and promulgated on August 26, 2021 specifies the nomenclature rules for *in vitro* diagnostic reagents regulated as medical devices as follows:

The product names of *in vitro* diagnostic reagents generally consist of three parts:

First part: The name of the substance to be tested;

Second part: The usage, e.g., diagnostic reagent kits and control materials, etc.;

Third part: The method or rationale, e.g., magnetic particles-based chemiluminescence enzyme immunoassay, fluorescence PCR, and fluorescence in situ hybridization, etc., and this part shall be listed in parentheses.

If the analyte has too many components or in case of other special circumstances, name of indications related to the product or other alternative name may be used. Class I products, calibrators and control materials shall be named according to their intended use.

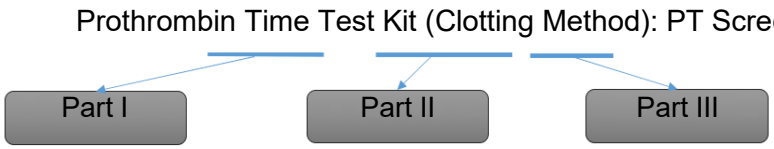



Figure 1 Nomenclature of *in vitro* diagnostic reagent

NMPA has formulated and issued nomenclature guidelines for 22 specific fields in accordance with the *Rules for Medical Device Nomenclature* and the *Guidance for Nomenclature of the Generic Names of Medical Devices*, aiming to guide the formulation of generic names of medical devices.

### 2.6 World Health Organization (WHO) Medical Device Nomenclature Practices

In 2007, Resolution WHA60.29 adopted at the 60th World Health Assembly mandated the WHO to develop and promote standardized terminology and guidelines for medical devices. According to the 2022 Global Atlas of Medical Devices published by WHO, approximately 52% of surveyed countries use at least one official medical device nomenclature system, while 49% of member states lack a national nomenclature system. The multiplicity of medical device nomenclature systems worldwide has also led to complexities in the procurement, supply, trade, and tracking of medical devices. Since then, WHO has continued to conduct research and member state consultations, identifying that an ideal nomenclature system should be globally accessible, transparent, and unified.

In terms of nomenclature system selection, WHO has clarified that it will not develop a new system, but will focus on coordinating existing international nomenclature frameworks. In 2022, the 75th World Health Assembly adopted Decision WHA75(25), which stipulates that medical device-related information (including terminology, codes and definitions) shall be integrated into WHO web-based databases and information exchange hub. Accordingly, WHO adopted the codes and terminology of the European Medical Devices Nomenclature (EMDN) in 2023, and added the terminology, codes and definitions of the Global Medical Device Nomenclature (GMDN) for concurrent use from March 2024. By adopting the two most widely applied international nomenclature systems, WHO aims to advance the unification and integration of global nomenclature standards. Launched by WHO in 2024 as an open-access database, the WHO Priority List of Medical Devices Information System (MeDevIS) serves as the platform for this integration.

MeDevIS consolidates priority medical device list previously dispersed across multiple publications covering key disease areas: reproductive, maternal, newborn and child health, cancer management, cardiovascular disease and diabetes care, as well as COVID-19 response. A continuous update mechanism is in place to incorporate new products selected based on the latest evidence-based guidelines. The official MeDevIS website (https://medevis.who-healthtechnologies.org/) offers free public access and data retrieval. It supports multi-dimensional queries by device type, clinical purpose, associated diseases, etc. Users can browse the hierarchical tree of priority medical device list and search by keyword of product names. The system simultaneously presents the codes, terms, and definitions of both EMDN and GMDN in the search results, facilitating comparison and use by different countries and institutions. To date, MeDevIS provides a unified search portal for more than 2,500 types of medical devices. Users can retrieve device codes, definitions, applicable scenarios and other data to support regulatory oversight, procurement and health emergency response decision-making by member states.

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