



DAPB4004 Global Medical Device Nomenclature (GMDN) for medical device identification

Requirements Specification

February 2023

Better data - better decisions

Data Alliance Partnership Board (DAPB)

The Data Alliance Partnership Board (DAPB), which holds delegated authority from the Secretary of State for Health and Social Care, has approved a new information standard for publication under [section 250 of the Health and Social Care Act 2012](#).

Assurance that this information standard meets the requirements of the Act and is appropriate for the use specified in the specification document has been provided by the Data Standards Assurance Service (DSAS) and endorsed by the Data Alliance Partnership Sub Board (DAPSB).

This information standard comprises the following documents:

- Requirements Specification
- Implementation Guidance.

An Information Standards Notice (DAPB4004 Amd 20/2021) has been issued as a notification of use, scope of the standard and implementation timescales. Please read this alongside the documents for the standard.

The controlled versions of these documents can be found on the [NHS Digital website](#). Any copies held outside of that area, in whatever format (e.g., paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

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Table of Contents

Contents

1	Glossary of Terms.....	4
2	Related /Supporting Information.....	6
2.1	Related Standards.....	6
2.2	Supporting Guidance.....	6
3	Scope.....	6
4	Definition.....	7
5	Purpose.....	8
6	Benefits.....	9
7	Requirements.....	11
8	Conformance criteria.....	11
9	Legal position.....	12
10	Timescales / Plan.....	13
11	Helpdesk.....	14
11.1	Contact Information.....	14
11.2	Useful resources.....	14
11.3	URLs used in this document.....	14

1 Glossary of Terms

Term	Definition
AIDC	Automatic Identification and Data Capture - a technology used to automatically capture data. AIDC technologies include barcodes, smart cards, biometrics and RFID.
Barcodes	Barcodes, also known as data carriers, are symbols which are encoded with data in a machine-readable pattern. They can be either a 1D (linear) or 2D format and are read with either laser or camera based scanners.
DAPB	Data Alliance Partnership Board - DAPB holds delegated authority from the Secretary of State for Health and Care to approve information standards and data collections for use in England
DAPSB	Data Alliance Partnership Sub Board – provides scrutiny of proposals for new and/or changes to information standards and data collections for use in health and care in England. The DAPSB makes recommendations for approval to DAPB.
UDI-Device Identifier	The Unique Device Identifier-Device Identifier (UDI-DI) is a unique numeric or alphanumeric code specific to a model of medical device and that is also used as the access key to information stored in a Master Data Management Systems or UDI database. Examples of the UDI-DI include GS1 GTIN (Global Trade Item Number).
DHSC	Department of Health and Social Care – a ministerial department that leads, shapes and funds health and social care in England, making sure people have the support, care and treatment they need, with the compassion, respect and dignity they deserve.
dm+d	Dictionary of medicines and devices (dm+d) The dm+d is a dictionary of descriptions and codes which represent medicines and devices in use across the NHS.
GMDN	The Global Medical Device Nomenclature. A collective description for the GMDN Term data set and associated data.
GMDN Agency	An organization representing the interests of regulatory agencies, manufacturers and healthcare providers to ensure the continued relevance and effectiveness of the GMDN, and is responsible for the development, control and distribution of the GMDN
GMDN Collective Term / Category	A GMDN Collective Term (CT) or Category provides a multi-hierarchical structure to the GMDN and supports the search for groups of GMDN Terms and thereby larger groups of Medical Devices, by using common features or characteristics.
GMDN Term	A basic data entity within the GMDN data set. A term consists of a code, name and definition. It is the data representation of a generic device group or set of devices having the same or similar intended use and common technology.

Term	Definition
GMDN Term Name	Concise phrase describing a medical device. Maximum 120 characters.
GMDN Term Code	Record identifier. Range 10000-69999
GMDN Term Definition	Description of the medical device's intended use, application, and technology. Maximum 700 characters
GS1	GS1 is a not-for-profit organisation that develops and maintains global standards for business communication. The best known of these standards is the barcode, a symbol printed on products that can be scanned electronically.
ISN	Information Standards Notice – is a notice of an Information Standard approved by the DAPB for use in health and care in England
Master Data record	A database record for a medical device that includes information about it. For example, the Manufacturer name, Catalogue number, device size, UDI-DI, GMDN Term, etc.
Master Data Management System	A database for Master Data for all the medical devices used.
Medical Device	Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings.
MHRA	The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices, and blood components for transfusion in the UK
MHRA DORS	MHRA Device Online Registration System is a database for registering medical devices before their use in Great Britain and Northern Ireland
NHSE	NHS England support the NHS to deliver improved care for patients.
ODS	The NHS Organisation Data Service is provided by NHS Digital and is responsible for publishing codes that identify organisations and individuals across health and social care.
RFID	Radio Frequency Identification (RFID) refers to a wireless system comprised of two components: tags and readers.
UDI	Unique Device Identifier (UDI) is a system intended to provide single, globally harmonized positive identification of medical devices through distribution and use

2 Related /Supporting Information

2.1 Related Standards

Related Standards **MUST** be used and read alongside this document.

Reference	Title
DAPB0108	Automatic Identification and Data Capture (AIDC)
DAPB3103	Surgical Devices and Implants Core Data Set

2.2 Supporting Guidance

Supporting Guidance **MAY** be used and read alongside this document.

Reference	Title
Version 2021-06-04	GMDN Terms Data Export Field Descriptions
IMDRF/UDI WG/N7FINAL:2013	IMDRF UDI Guidance. Unique Device Identification (UDI) of Medical Devices
Version January 2021	MHRA Managing Medical Devices. Guidance for health and social care organisations
Version 21.0.1	GS1 General Specifications
Version February 2023	DAPB4004 Global Medical Device Nomenclature (GMDN) for medical device identification - Implementation Guidance

3 Scope

The GMDN is used in all healthcare settings, including NHS primary, secondary and tertiary healthcare in England where medical devices are used. It therefore applies to all healthcare IT applications used by the NHS in England that develop and implement systems which manage medical device inventory.

The users of the standard will be primarily those involved in the design, manufacture, procurement, deployment and use of systems which manage medical devices.

These may include:

- IT and informatics personnel
- Finance and procurement
- Departmental directors and managers
- Project managers
- Healthcare professionals
- Administration staff
- Facilities Management
- Arms Length Bodies (ALB)

4 Definition

The Global Medical Device Nomenclature (GMDN) is a list of generic names used to identify all medical device products. Such products include those used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans.

The GMDN is a Fundamental standard, like the dictionary of medicines and devices (dm+d). It is used to name the different types of medical device products used in a healthcare setting, for example surgical instruments, patient monitors, disinfectants, cardiac pacemakers, stents, beds, diagnostic kits, and medical software.

The GMDN Term is a generic device concept that is used to name and group technically similar medical devices and includes a precisely defined Term Name and Term Definition, as seen in this example:

GMDN Term Name: Scalpel, single-use

GMDN Term Code: 47569

GMDN Term Definition: A sterile, hand-held, manual surgical instrument constructed as a one-piece handle and scalpel blade (not an exchangeable component) used by the operator to manually cut or dissect tissue. The blade is typically made of high-grade stainless-steel alloy or carbon steel and the handle is often made of plastic. This is a single-use device.

A 5-digit numeric GMDN Code is used with the Term Name and Term Definition to aid the identification of the GMDN Term.

The GMDN Term is a generic device name and independent of manufacturers' proprietary names or identifiers. Medical devices cover a wide range of technologies and materials. The GMDN has over 24,000 separate generic names for all the medical products. The GMDN does not cover drugs but does refer to drugs used in drug/ device combination products, for example drug-eluting stents and also In vitro Diagnostic Devices (IVDs).

The GMDN is maintained by the GMDN Agency. There is a quality procedure in place to manage the updating of the GMDN Terms and this is part of their ISO9001 Quality Management System that is certified by a third party.

The use of an internationally recognised nomenclature is an important step in this process

There is no cost associated with access and use of the GMDN by the NHS.

Data collection is **not** required for this standard. The application standards, such as [DAPB3103 Surgical Devices and Implants Core Data Set](#) , provide information about how data is collected to meet a specific requirement.

5 Purpose

The GMDN Term is the generic or common name for a medical device. It is used to make the naming and grouping of medical devices more consistent. The many-to-one relationship between the GMDN Term and a group of similar products from different manufacturers can be seen in the graphic below.

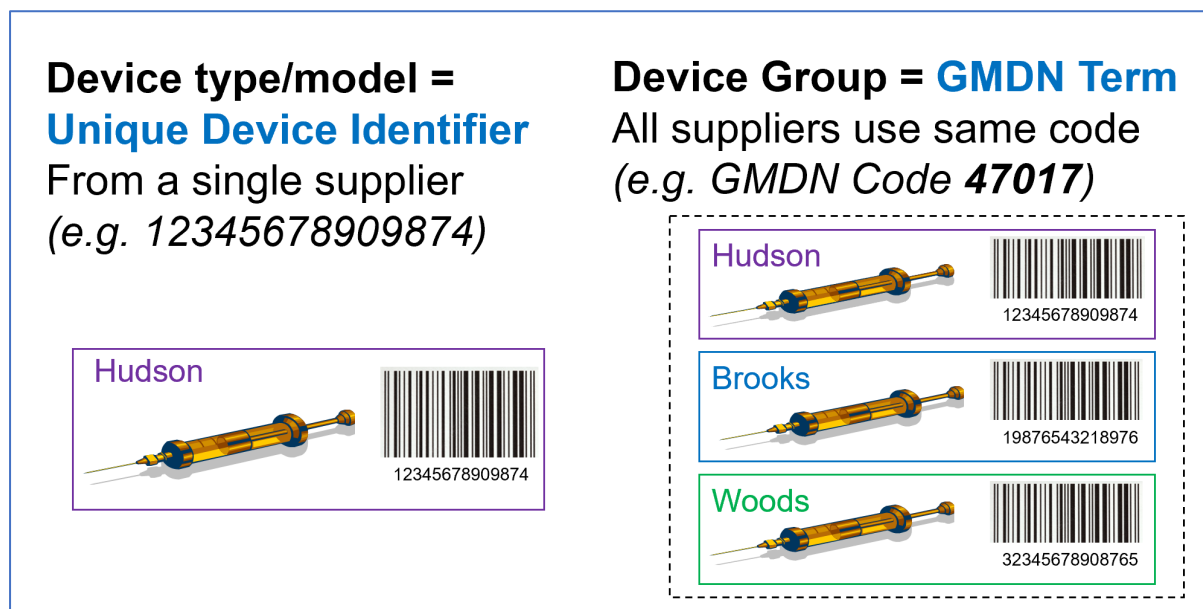


Fig. Example of the many-to-one relationship

Because the GMDN is an international standard, the naming of medical devices can be done at a global level. This enables problems with medical devices to be identified and shared between users in different countries in a consistent way. Consistent naming is also beneficial at a national level.

The GMDN is used in many other countries including the USA, Canada and Australia.

The main purpose of the GMDN is to provide health authorities and regulators, health care providers, manufacturers and patients with a naming system that can be used to exchange medical device information and support patient safety.

The GMDN is used to support the:

- Transfer of information between manufacturers, regulators and healthcare authorities
- Exchange of post-market vigilance information
- Supporting inventory control in hospitals
- Purchasing and supply chain management
- Supporting decisions concerning product recall

The GMDN is selected by the device manufacturer and is provided to the device regulator, such as the MHRA and then the device user, such as the NHS, as an attribute.

The GMDN Term should be linked to each medical device that is supplied to the NHS. To improve the efficiency, consistency, and accuracy of this process the following process is used:

1. A medical device manufacturer identifies the GMDN Term for each of their products
2. The medical device information, including the Unique Device Identifier (UDI), manufacturers name, catalogue number, device description and GMDN Term is provided to a national device register database, such as that used by the MHRA
3. The medical device information is provided to the hospital from the national device register

This means NHS Staff do not have to categorise the medical device themselves and errors and inconsistency in naming can be reduced.

When a problem with a medical device is detected and reported, having an accurate and consistent medical device name will help determine the cause of the failure and extent of the problem. Consistent naming of medical devices could also help to improve management of inventory and awareness of new medical technology.

The GMDN Terms are maintained by the GMDN Agency with input from medical device manufacturers, who are required by national device safety regulations, such as the UK 'Medical Devices Regulations 2002' to identify their products using a standard nomenclature.

6 Benefits

The GMDN Term is the standard name for medical devices. It is the primary device nomenclature used for categorising medical device and related equipment and communicating this consistently across the NHS. The GMDN is also used by the MHRA to identify device types and group medical devices and analyse device safety. Specific users within the NHS, for example Clinical Engineering, are also currently using the GMDN to identify and manage medical equipment.

There has been a long-standing aim of national regulators of medical device safety (see [IMDRF UDI Guidance](#)) to compare devices with similar characteristics and thereby exchange meaningful information about adverse incidents. The use of an internationally recognised nomenclature is an important step in this process. The MHRA are the sponsors for this standard and currently, when registering medical devices with the MHRA and when reporting medical device adverse incidents to the MHRA, manufacturers or their UK Responsible Person must submit a GMDN code to identify the medical device. MHRA has long considered GMDN to be the best option for medical device nomenclature for the UK system. It is widely used worldwide, and it is required by the US, Canada, Australia, Singapore, and other nations in regulatory submissions and UDI databases.

The MHRA recently consulted with stakeholders about new regulations for medical devices supplied to the UK, which includes the choice of device nomenclatures. The Government response to the consultation on the future regulation of medical devices was published in June 2022 and concluded “Having considered the views of respondents, the government intends to proceed with the proposal to require that manufacturers provide the MHRA with the relevant GMDN nomenclature for their medical device (including in vitro diagnostic medical devices) as part of device registration.”

More information can be found on the [consultation on the future regulation of medical devices in the United Kingdom](#).

The draft regulation is expected to be available in 2023.

The [Independent Medicines and Medical Devices Safety Review](#) Chaired by Baroness Cumberlege, provided recommendations including “The MHRA should keep a register of all devices approved for the UK market.”

In written evidence to the Review, NHS Digital said “In addition when things go wrong there needs to be a way of tracking the supply chain using GMDN...”

The NHS can use the GMDN in their data systems to better identify, name and group medical devices. The GMDN provides a standardised name that is non-proprietary to help the NHS be consistent in identifying and recording the device they use with patients. This consistency further helps in the tracking of the safety and efficacy of devices and therefore supports better outcomes for patients.

The GMDN is complementary to the Device Identifier (UDI-DI), such as GS1 GTIN, (which identifies the individual medical device supplied by one manufacturer). The UDI-DI is the numeric representation of a AIDC or barcode that is to be found on a medical device or its packaging that identifies the individual device. The GS1 organisation provide manufacturers with the UDI-DI numbers. The use of barcodes to support patient care is explained in the [NHS Scan 4 Safety programme](#).

The association between the GMDN Term and the specific device, identified by a UDI, is made by the manufacturer when they register the device with the MHRA. This is beneficial to the NHS because it removes the burden of this task from NHS staff and will improve consistency too.

GMDN Terms for medical devices have been incorporated into [SCCI0034: SNOMED CT](#) mainly for surgical implants and related devices that may be included in electronic patient records.

Examples of Use

Example of use 1. A clinical engineer has identified a patient bedside monitor they need to calibrate using a locally defined asset number. That asset number has an entry on a system the hospital uses to manage and schedule the regular maintenance of all equipment. The GMDN is used in the system to name and group the asset, irrespective of the manufacturer. This helps to identify all the similar bedside monitors and is useful to ensure the hospital has sufficient to meet their

needs, which is very important for emergency planning and response, which was a challenge during the recent Covid-19 pandemic.

Example of use 2. A nurse needs a certain dressing for a patient and has run out at their station. That brand of dressing (identified by the GS1 GTIN) is out of stock in the hospital. Using the GMDN, the stock control system can identify a similar dressing from a different manufacturer (with a different GS1 GTIN), but which is located in the nearby stock room, thereby solving their immediate problem.

Example of use 3. A patient has a recently implanted artificial knee. The medical device implanted is identified with a UDI-DI (GS1 GTIN) and the patient has a card they carry with that information. When they are on holiday the patient experiences severe pain and contacts a local hospital to seek advice. The clinical staff are able to use the UDI-DI in their health system to identify the device more quickly using the related GMDN Term and therefore better understand the type of knee joint used during the implant procedure. The doctor is then able to provide the correct advice for treatment.

7 Requirements

It is important to understand that the GMDN is not itself a list of medical device products. The GMDN is a nomenclature that is matched to the medical device products by the supplier.

When using a GMDN the following are required:

1. Identify the central database for medical device used by your facility.
2. Ensure that all the medical devices used in your facility have a UDI-DI and it is recorded in the central database.
3. Ensure all medical devices in the database have a GMDN Term assigned.
4. If the medical device does not have a UDI-DI and GMDN Term assigned, contact the device manufacturer or central database administrator.
5. If you have concerns that the medical device does not have the appropriate GMDN Term assigned contact the manufacturer or central database administrator.

8 Conformance criteria

1. All medical devices must have a UDI-DI. It is NHS England procurement policy to ensure a UDI-DI, such as a GS1 GTIN, is printed on the product packaging. If the UDI-DI is missing, please contact your procurement department for advice.
2. All medical devices must have a GMDN Term allocated. This should be provided by the supplier when the device is purchased.

The following examples are typical uses of the GMDN, and specific requirements are provided.

Example 1 Medical Device Inventory Management

The management of inventory, such as surgical consumable items, is a resource management process and starts with the purchasing team to identify the GMDN Term for all the medical device items they purchase. Medical device manufacturers need the GMDN Term to register their products with the MHRA before they are legally allowed to sell them in the UK.

The purchasing team will receive the GMDN Term with other product information supplied by the manufacturer during the pre-purchase stage. The GMDN Terms are part of the [NHS England Medical Device Information System \(MDIS\)](#), that should include the device UDI-Device Identifier (such as a GS1 GTIN) and other product and safety related information. The information in the Master Data record will be uploaded to the hospital resource management system to allow purchasing and then inventory control management system to control and replenish stocks.

Example 2 Medical Technology Asset Management

Asset management in hospitals is usually accomplished by labelling individual items of equipment with a unique identity and use of an asset management software application to list the item and its associated information to support maintenance, repair, calibration, and general management of the equipment.

The GMDN is information that helps identify the type of equipment and thereby group all similar equipment. This would for example, help to identify the total number of respiratory masks or syringe drivers in a hospital and therefore support device planning for the future. Usually, the GMDN Term would be identified and supplied by the device manufacturer or identified by the Clinical Engineering team if necessary. Only one GMDN Term would be associated with any single piece of equipment.

Further information about the use of GMDN can be found in the 'Implementation Guidance' document.

9 Legal position

The GMDN is a non-mandatory standard.

Since 1 January 2021 there is a requirement to register with the MHRA all medical devices available for supply to the UK market. These requirements have been introduced by the MHRA using statutory powers contained in the Medicines and Medical Devices Act 2021 (see section 16) and Medical Devices Regulations 2002, as amended. The GMDN is a mandatory requirement for medical device registration. A GMDN Term is selected and supplied by a manufacturer when they register their product type in the MHRA registration system. This process is continuous as new products reach the UK market and are available for supply.

The MHRA use the GMDN Term to identify the generic group of the devices they are regulating. This is used to specifically determine if an adverse event caused by a

device might be specific (to one manufacturer's type of device) or generic (typical of all similar devices). This will indicate the best approach to mitigate the fault.

In future it is planned that the NHS will get medical device Master Data, including the GMDN Term directly from the MHRA.

The GMDN data set is currently available under licence for use by all the NHS, its staff and contractors.

Wherever the Licensee publishes or displays any GMDN Terms, the Licensee shall display with reasonable prominence a proprietary notice in accordance with the following wording:

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The statement should be reviewed annually, and the date updated to the current year. Alternative wording to the above statement, should be agreed in writing with the GMDN Agency.

The GMDN Term is required to be supplied by device manufacturers when they provide their other product information to the NHS (or one of their agents) prior to authorisation of a purchase agreement or contract. As such the GMDN Term is subject to contract law as a trade description.

For guidance on access to the GMDN Terms, please refer to the [DAPB4004 Implementation Guidance](#).

10 Timescales / Plan

The GMDN data is available to be used by the NHS and its medical device suppliers already. The GMDN is continuously updated as new medical device technology becomes available and updates are published in daily and in monthly tables.

The NHS database applications that make use of the GMDN, such as [DAPB3103: Surgical Devices and Implants Core Data Set](#) will be updated automatically and it is expected uses of these applications will not have to update the new GMDN Terms as they are published.

At any time, NHS users of the GMDN can obtain an updated dataset from the GMDN Agency Helpdesk on request.

11 Helpdesk

11.1 Contact Information

For further information and support on DAPB4004: Global Medical Device Nomenclature, please note the following details:

Developer	
Organisation	GMDN Agency
Webform	GMDN Agency contact form
Phone	01235 799759 (Mon–Fri 10am–3pm)

11.2 Useful resources

Visit the [GMDN Agency website](#) to obtain free access to the GMDN Term and Codes for medical devices. The website provides a comprehensive Terms browser and a free enquiry service for help and advice on the use of GMDN. If a new GMDN Term is needed, there is a free ticketing service to manage this process.

11.3 URLs used in this document

DAPB4004 Global Medical Device Nomenclature (GMDN) for medical device identification - Implementation Guidance	https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dapb4004-global-medical-device-nomenclature-gmdn Short URL: https://digital.nhs.uk/isce/publication/dapb4004
NHS Organisation Data Service	https://digital.nhs.uk/services/organisation-data-service
GMDN Terms Data Export Field Descriptions	https://www.gmdnagency.org/assets/about/resources/GMDN%20Agency%20Terms%20Data%20Export%20Field%20Descriptions%202021-06-04.pdf
IMDRF UDI Guidance. Unique Device Identification (UDI) of Medical Devices	http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf
MHRA Managing Medical Devices. Guidance for health and social care organisations	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/982127/Managing_medical_devices.pdf
GS1 General Specifications	https://www.gs1.org/docs/barcodes/GS1_General_Specifications.pdf

Consultation on the future regulation of medical devices in the United Kingdom	https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom
Independent Medicines and Medical Devices Safety Review	https://www.immdsreview.org.uk/
NHS Scan 4 Safety programme	https://www.scan4safety.nhs.uk/index.html
NHS England Medical Device Information System (MDIS)	https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/national-perioperative-data-standard-programme#medical-device-information-system-mdis
DAPB3103: Surgical Devices and Implants Core Data Set	https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dapb3103-surgical-devices-and-implants Short URL: https://digital.nhs.uk/isce/publication/dapb3103
DAPB0108: Automatic Identification and Data Capture (AIDC)	https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dapb-0108-automatic-identification-and-data-capture-aidc Short URL: https://digital.nhs.uk/isce/publication/dapb0108
GMDN Agency website	https://www.gmdnagency.org
GMDN Agency Helpdesk	https://www.gmdnagency.org/help/contact
SCCI0034: SNOMED CT	https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/scci0034-snomed-ct Short URL: https://digital.nhs.uk/isce/publication/scci0034