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

Implementation Guidance

February 2023

Better data - better decisions

Data Alliance Partnership Board (DAPB)

This information standard (DAPB4004) has been approved for publication on behalf of the DAPB by the Data Alliance Partnership Sub Board (DAPSB) 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) which makes recommendation for approval of information standards and data collections to the DAPSB.

The DAPSB has delegated powers of approval granted to it by the DAPB which in turn acts on behalf of the SoS for Health and Care.

This information standard comprises the following documents:

- Requirements Specification
- Implementation Guidance.

An Information Standards Notice (DAPB4004) has been issued as a notification of use 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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Copyright Statement

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1. Related /Supporting Information

1.1 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

1.2 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 - Requirements Specification

2. Scope

The Global Medical Device Nomenclature (GMDN) is used in all healthcare settings, including NHS and private providers, 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)

3. Definition

The GMDN is a set of standardised names that are used to make the naming and grouping of medical devices more consistent. 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 countries in a consistent way. Consistent naming can also be useful at a national level. The GMDN is selected by the device manufacturer and is provided to the device user, such as the NHS, as an attribute. This means NHS Staff do not have to categorise the medical device themselves. When a problem with a medical device is detected, having an accurate and consistent generic name will help determine the cause of the failure.

4. 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.

5. Implementation Guidance by User Group

5.1 General plan for using GMDN

All users will benefit from planning the implementation of GMDN, using the following list as a guide:

1. Read DAPB4004 Global Medical Device Nomenclature for medical device identification, Requirements Specification, and Implementation Guidance

2. Read GMDN supporting guidance (see 1.2)

3. Consider the local situation to determine if the GMDN is already available for your intended application, for example the GMDN Terms may already be available as part of a SNOMED dataset, such as described in SCCI0034: SNOMED CT or it may be

already incorporated as part of an implementation standard such as DAPB3103: Surgical Devices and Implants Core Data Set

4. Develop implementation plan, if appropriate

5. Contact the GMDN Agency who can provide direct access to the GMDN data set, including Term Names, Definitions and Codes.

6. Review your implementation plan at regular intervals

5.2 GMDN use for all new users

It is expected that the GMDN would be used within a system designed specifically for its inclusion, such as relational database application. Such systems will be for example an inventory management system or procurement system. The application should collate and present GMDN Terms in relation to the specific device of interest. The use of Unique Device Identifiers (UDI-DI), such as GS1 GTIN (see section 6.3), on every device purchased for use by the NHS and / or an asset number that should identify all existing medical equipment, where a Device Identifier is unavailable, should enable the creation of a Master Data Management (MDM) system. The MDM system is a database which lists all medical devices used in a healthcare facility. All individual device records should be cross-referenced to only one GMDN Term Code.

An example of such a system is described in DAPB3103 Surgical Devices and Implants Core Data Set.

The GMDN Term Code should be held in a separate database table that would include other related data fields including, GMDN Term Name and GMDN Term Definition.

See file GMDN Terms Data Export Field Descriptions for information related to data structure.

The GMDN Terms would be available from the MDM system in the healthcare facility, but if that is not available, the whole GMDN Terms data set is available directly from the GMDN Agency at the GMDN Agency website.

The GMDN Terms are also submitted by device manufacturer to the MHRA as part of the UK regulations for registering medical devices for the UK market. More information can be obtained from the MHRA Register medical devices website

Other sources of medical device Master Data will become available as the use of the GMDN becomes more established. Such as the National Perioperative Data Standard Programme and The Medical Device Safety Programme .

It is expected that the Master Data file for medical devices would be available in the following type of data elements which relate to a specific type of device from single supplier. The Unique Device Identifier (UDI-DI) would act as a table index. This

information would ideally originate from the device manufacturer. Only one GMDN Code should be included for each item.

UDI-DI	Supplier	Brand	Catalogue No	GMDN Code
11111111111	AAAAAAAA	AAAA	66666	40599
22222222222	BBBBBBBB	BBBB	77777	35177
33333333333	CCCCCCC	CCCC	88888	45171
44444444444	DDDDDDD	DDDD	99999	36740
55555555555	EEEEEEEE	EEEE	11111	37704

The GMDN Code should cross reference to a table containing the GMDN Term Name and Term Definition. This table is available directly from the GMDN Agency.

GMDN Code	GMDN Term Name	GMDN Definition
40599	Instrument storage cabinet	A furniture-like device designed for general-purpose…
35177	Surgical/medical face mask, single-use	A flexible, loose-fitting mask designed to be placed…
45171	Dry medical towel/wipe, single-use	A dry fabric intended to be used to wipe or…
36740	Electroencephalographic signal amplifier	An electrical device that amplifies the signal level and…
37704	Anaesthesia breathing circuit, single-use	An assembly of devices designed to conduct…

5.3 GMDN use by existing users

Existing users of GMDN will be familiar with its structure and data elements. The GMDN Agency website provides a browser to check the current description for any GMDN Code, including the GMDN Terms Name and Definition.

The GMDN may already be included in an existing application. Such a system is described in DAPB3103 Surgical Devices and Implants Core Data Set .

5.4 GMDN use with SNOMED CT

Some GMDN Terms for medical devices have been incorporated into SCCI0034: SNOMED CT since 2012 when an agreement was signed between the GMDN Agency and SNOMED. The relationship between the GMDN Code and SNOMED Code will help to link the medical device supply chain to the application of care to individual patients for medical device, patient risk and safety use cases.

Approximately 8,500 GMDN Terms are incorporated into SNOMED CT, mainly for surgical implants and related devices that may be included in electronic patient records. The GMDN Codes are renumbered to the SNOMED CT format. The SNOMED CT data set for Physical Objects containing the GMDN is updated twice annually.

A free Linkage table is available for SNOMED International members (including the NHS) to understand the relationship between the GMDN and SNOMED CT codes.

More information is available from the GMDN Agency Helpdesk .

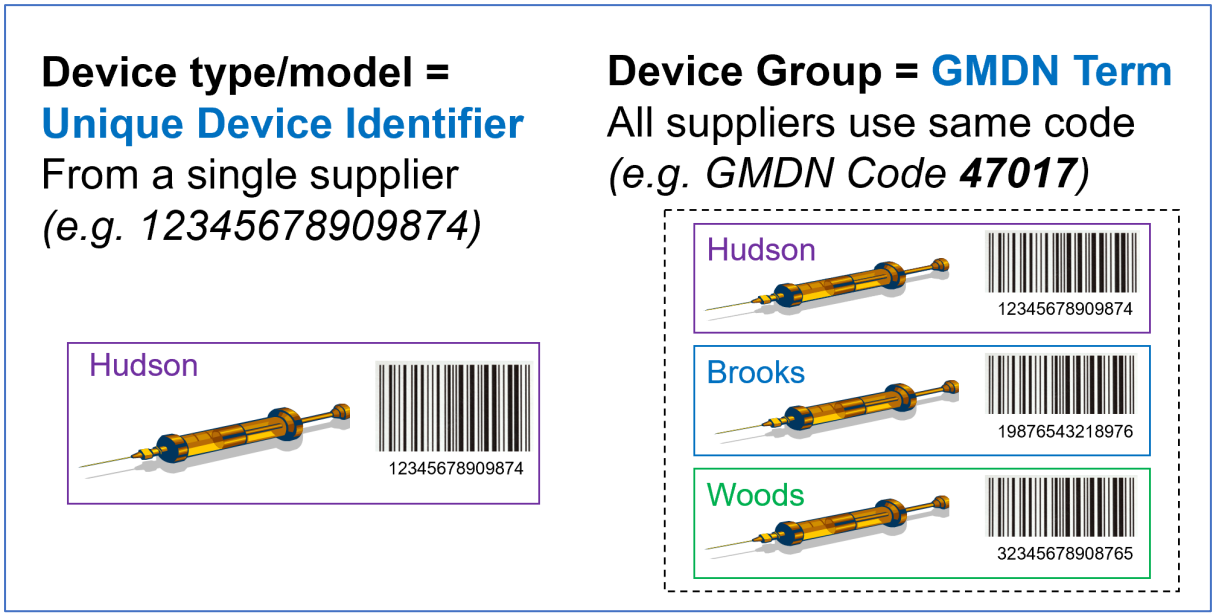
5.5 GMDN use with Unique Device Identifiers

Unique Device Identifiers (UDI) were introduced to the NHS under the NHS Scan 4 Safety programme. The UDI is encoded into the medical device or its packaging in the form of a barcode. The UDI numbers themselves are licensed to manufacturers from a globally recognised agency, such as GS1 General Specifications who impose strict rules to ensure the use of a number on a product (such as the GS1 GTIN) is globally unique and traceable to a single supplier.

The number on the product is cross-referenced to information about the product, such as the suppliers name, proprietary description, and other commercial and safety information. This information is normally held in a database and retrieved by an application when the barcode is scanned.

The GMDN Term is a generic description which is shared by medical devices that have a similar function. The GMDN Term Name, Definition and Code are also stored in a database and can be retrieved when the UDI is scanned.

The relationship between the data is provided in the diagram below.



5.6 Training

Training and support on the use of the GMDN and how it should be deployed in a database application is available free of any charge from the GMDN Helpdesk

5.7 Maintenance of the GMDN

The GMDN Terms are available for the NHS to use in all its systems **free of charge.**

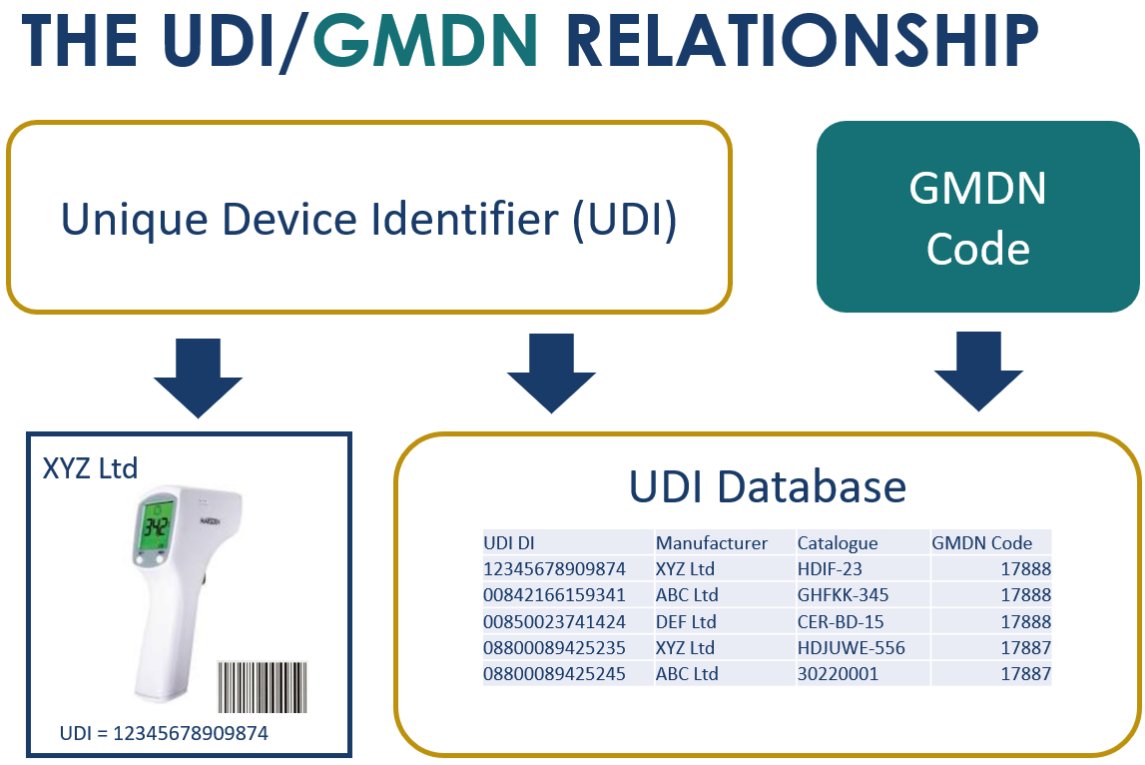
The GMDN data may be provided to the NHS by its suppliers, as part of the data set which accompanies the products or directly from the GMDN Agency. Data from the GMDN Agency is available in monthly downloadable files from the GMDN website.

It is recommended that in the case of doubt concerning the authenticity of the GMDN data provided, users are referred to the GMDN Agency website where GMDN Terms can be checked against the central database GMDN Agency website

5.7.1 How should I maintain my GMDN Data set?

It is expected that the GMDN would be used within a system designed specifically for its inclusion, such as relational database application. Such systems will be for example an inventory management systems or procurement system. The application should collate and present GMDN Terms in relation to the specific device of interest.

The use of Unique Device Identifiers, such as GS1 GTIN, on every device purchased for use by the NHS and / or an asset number that should identify all existing medical equipment, where a Device Identifier is unavailable, should enable the creation of a Master Data Management (MDM) system. The MDM system is a database which list all medical devices used in a healthcare facility. All individual device records should be cross-referenced to only one GMDN Term Code.



The GMDN Term Code should be held in a separate database table that would including other related data fields including, GMDN Term Name and GMDN Term Definition.

See file GMDN Terms Data Export Field Descriptions for information related to data structure.

5.7.2 Maintenance of the GMDN

The GMDN is a dynamic set of data, which is updated before new medical device products are placed in a market. The following section explains how the GMDN is maintained and updated.

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.

There are a huge range of technologies used in the MedTech industry, everything from specialist metals and plastics, machinery, electronics, chemicals and software. The industry is especially innovative and request the GMDN Agency to update the GMDN to include their latest device or product features every day.

The GMDN Agency employs a team of highly qualified technical authors to investigate how the technology works and to create a concise description, not too vague and not too prescriptive or proprietary. The language used should be accessible to non-experts, with no jargon or too many complex acronyms and the terminology and style should be consistent.

The GMDN has been used for many years and therefore there is large existing set of descriptions. As new products enter the market, the descriptions for these are ‘fitted-in’ to the nomenclature, not just added to the bottom of the list, as that risks the duplication of Terms. If a product is innovative and truly unique, the procedure is quite straightforward to add a new Term. Often the product is a small variant of an existing product and an amendment to the Term Name or Definition is allowed, but only if the original scope of the Term is not reduced, which might exclude products that may have previously been described by the Term.

Occasionally technology leaps forward and the GMDN Agency may need to review a set of GMDN Terms to determine if they reflect the current devices on the market, especially if the older technology is still commonly in circulation. In this case the GMDN Agency may introduce several new Terms and amend Terms and may make a Term obsolete, but this is quite rare (annually less than 1% of Terms are obsoleted). Obsoleted Terms remain available for historic reference / analysis purposes and remain linked to our higher-level Collective Terms too.

With so many variables, there is not a simple set of rules to determine when a new GMDN Term is created or amended. The following case studies describe some common scenarios we often come across.

GMDN may already be maintained as part of an existing NHS application, for example the GMDN Terms data updates are available as part of a SNOMED dataset, such as described in SCCI0034: SNOMED CT or an implementation standard such as DAPB3103: Surgical Devices and Implants Core Data Set

5.7.3 GMDN Term change examples:

For a New Product

Company A is planning to launch a new product which is very innovative. They search through all the relevant existing Terms in the GMDN website by carefully reviewing the Term Definition and none adequately describe their new product. They send the GMDN Agency an Enquiry and attach the relevant product description. A GMDN Term Developer who is experienced in the product technology and application, reviews the product specification, and reviews the existing GMDN Terms for similar products. If we consider that the product requires a new GMDN Term and enough information is provided, a draft GMDN Term is provided to Company A to review. At the same time, the new GMDN Term is displayed on the GMDN website 'Proposed' Term's list for any GMDN Member to provide a comment. Once the consultation period ends, the new Term is linked to the relevant Collective Terms and published.

A Product Variant

Company B has updated its design of a product. The product has a new feature. Company B reviews the GMDN Term it previously used for this product, but the new feature does not seem to be included. There is no other GMDN Term that is suitable either. They submit an Enquiry and usefully refer to the existing Term and identify where the variation in the Definition could be made, in their opinion. The GMDN Term Developer reviews the product information and the similar GMDN Terms and decides if an amendment to the existing Term will be the best solution. Amendments are not always made if the new product feature is minor or cosmetic. A Term amendment is drafted and provided to Company B to review. There is no consultation period with Term amendments because the change should not affect the suitability of the Term for any existing users. When published, the Term amendment notification is provided to members who opt for this service. All members who subscribe to Alerts also receive a monthly newsletter which list all the amendments that are relevant to the Terms they use. Amendments can be seen in the Details page for each GMDN Term with a summary note of the changes made.

A major review of Terms

Company C has developed a new product that is functionally like other products on the market, but it includes a novel electronic control system that improves patient care. There are now similar devices that have electronic control and those that do not. Company C submits an Enquiry and the GMDN Term Developer decides, in consultation with the manufacturers of similar devices, to make two new GMDN Terms to distinguish between the two variants of product type, 'manual' and 'electronic control'. The existing GMDN Term is made obsolete because it no longer

represents a single product group. As with Term amendments, users of the existing Term are notified by email that it has been made obsolete and are directed to use one of the two new Terms.

We can see from these case studies that decisions about Term changes are made in consultation with the manufacturers and if necessary, a consensus is reached after wider consultation, sometimes with regulators input. The timespan necessary from the Enquiry being submitted to us to the publication of any change is dependent on the complexity of the product, the responsiveness of the applicant to any question we have and the impact of any changes on the GMDN database. The GMDN Agency aim to complete the processes as soon as possible, because we know regulators and manufacturers are waiting to use the GMDN Terms to register their products and make them available to patients.

6.Helpdesk

6.1 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)

6.2 Useful resources

Visit the GMDN Agency website to obtain free access to the GMDN Terms 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 Enquiry ticketing service to manage this process.

6.3 URLs used in this document

DAPB4004 Global Medical Device Nomenclature (GMDN) for medical device identification – Requirement Specification	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
SNOMED International	https://www.snomed.org/
MHRA Register medical devices	https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market
National Perioperative Data Standard Programme	https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/national-perioperative-data-standard-programme

Medical Device Safety Programme	https://www.gettingitrightfirsttime.co.uk/girft-to-harness-technology-to-improve-medical-devices-safety/
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