UDI, REGULATORY DATABASES AND GMDN UTILISATION

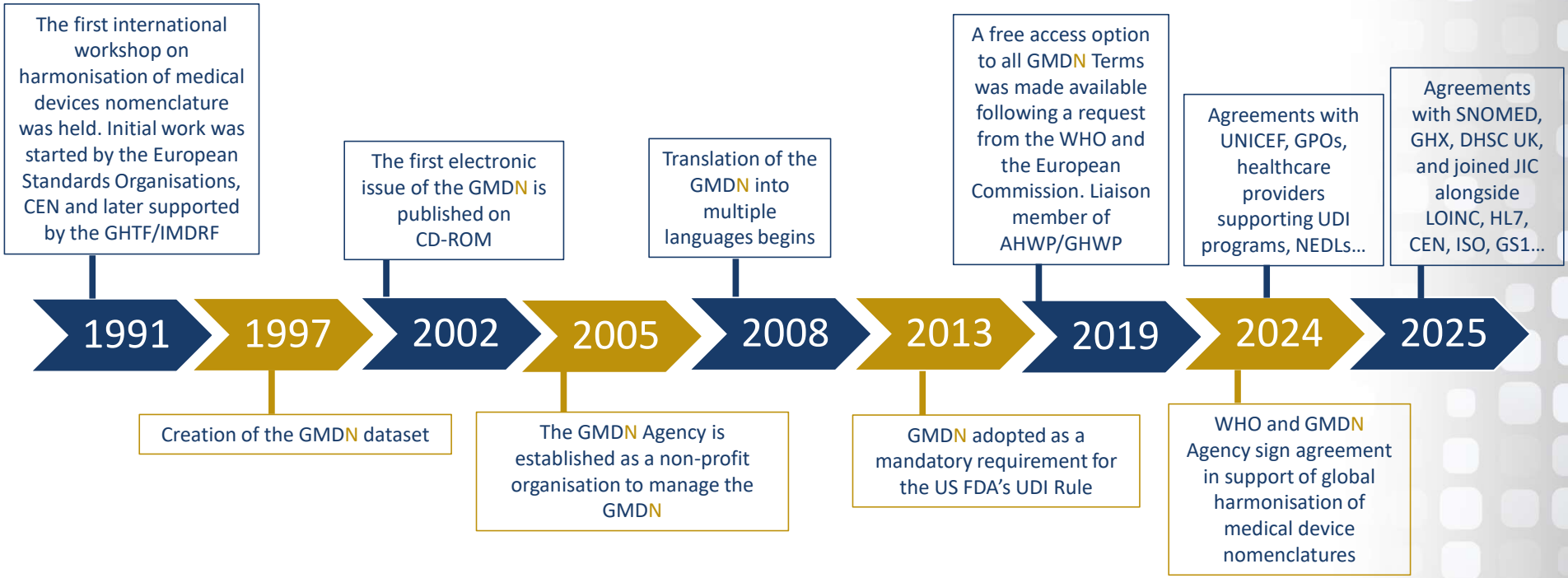
GS1 UK MEDICAL DEVICE SUPPLIER FORUM 2026
03 FEBRUARY 2026

DENIZ BRUCE - CEO

STANDARDISED NOMENCLATURE IS ESSENTIAL FOR MAINTAINING PATIENT SAFETY AND PROMOTING BETTER HEALTHCARE OUTCOMES.

GMDN AGENCY - OUR JOURNEY

A NON-PROFIT, CHARITY*



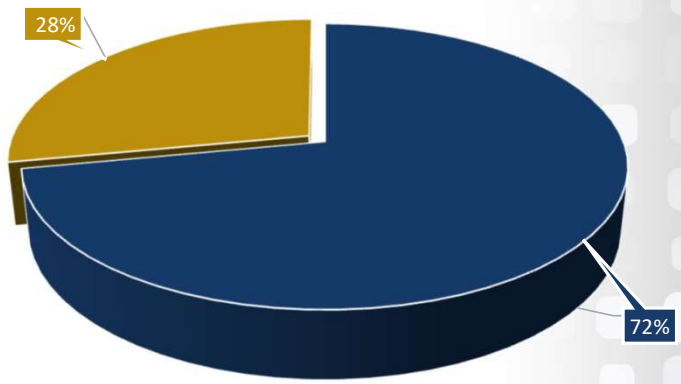
* https://register-of-charities.charitycommission.gov.uk/en/charity-search/-/results/page/1/delta/20/keywords/GMDN

Ref.: https://www.imdrf.org/ghtf/history

WHAT WE DO
GLOBAL MEDICAL DEVICE NOMENCLATURE (GMDN)
A NON-PROFIT, CHARITY

- >30 years of experience in nomenclature development and maintenance
- >13 years of UDI implementation experience
- Independent and guided by Regulators
- Supported by voluntary Members
- Name and Group All Medical Devices
  - Well-defined, mutually exclusive concepts
  - Grouping at many levels of granularity
  - Up-to-date
  - Training and Term Enquiry service for all users
- Register for GMDN and access the database. Free access for all Regulators/Governments, Hospitals. Membership options (incl. free of charge) are available: https://www.gmdnagency.org

GMDN Reach and Use in 139 of 194 Countries*



*Dec 2025: Registration/membership info is in real-time.

Management and maintenance of the GMDN Database is monitored and controlled by an ISO9001 Quality Management System.
Our QMS is annually audited by a third-party Certification Body. The GMDN Agency has internal QMS and SOPs regarding Term development, management of GMDN Term Enquiries, translations, stakeholder/Regulator consultation and management of conflicts.

GMDN USE – GOVERNMENT DEPARTMENTS

Argentina
Armenia
Australia
Azerbaijan
Bahrain
Bangladesh
Bhutan
Bosnia and Herzegovina
Botswana
Brazil
Burkina Faso
Canada
Chile
Colombia
Cuba

EEU
Ecuador
Egypt
El Salvador
Eritrea
Ethiopia
Ghana
Guyana
Honduras
Iceland
India
Iran
Japan
Kazakhstan
Kenya

Kuwait
Kyrgyzstan
Lebanon
Libya
Macau
Malaysia
Mexico
Mongolia
Mordovia
Mozambique
New Zealand
Nigeria
Norway
Oman
Pakistan

Peru
Philippines
Russia
Rwanda
Saudi Arabia
Singapore
Somalia
South Africa
South Korea
Sudan
Switzerland
Tanzania
Thailand
Tunisia
Turkiye

Uganda
Ukraine
United Kingdom
United States
Uruguay
Uzbekistan
Vietnam
Yemen

***Dec 2025: Registration/membership info is in real-time.**

WHAT DOES A MEDICAL DEVICE NOMENCLATURE DO?

- Provides a **standardised system** for naming, categorising and identifying all types of medical devices.
- **Empowers** the public and all stakeholders to understand their medical devices
  - Supports strategic planning and oversight of global access to medical devices – especially in developing countries
- Enables **interoperability**, linking medical device data across different health systems and stakeholders
- **Complements UDI**:
  - Traceability in-country and across jurisdictions
  - Enables early signal detection of medical device performance issues: Category-level analysis; it lets us understand trends across categories
  - Enables data analysis - pooling data from pre-market and post-market surveillance programs
  - Enables identification of the right technology for the patient
- Improves **decision-making and operational effectiveness**

Reliance
Convergence
Harmonisation

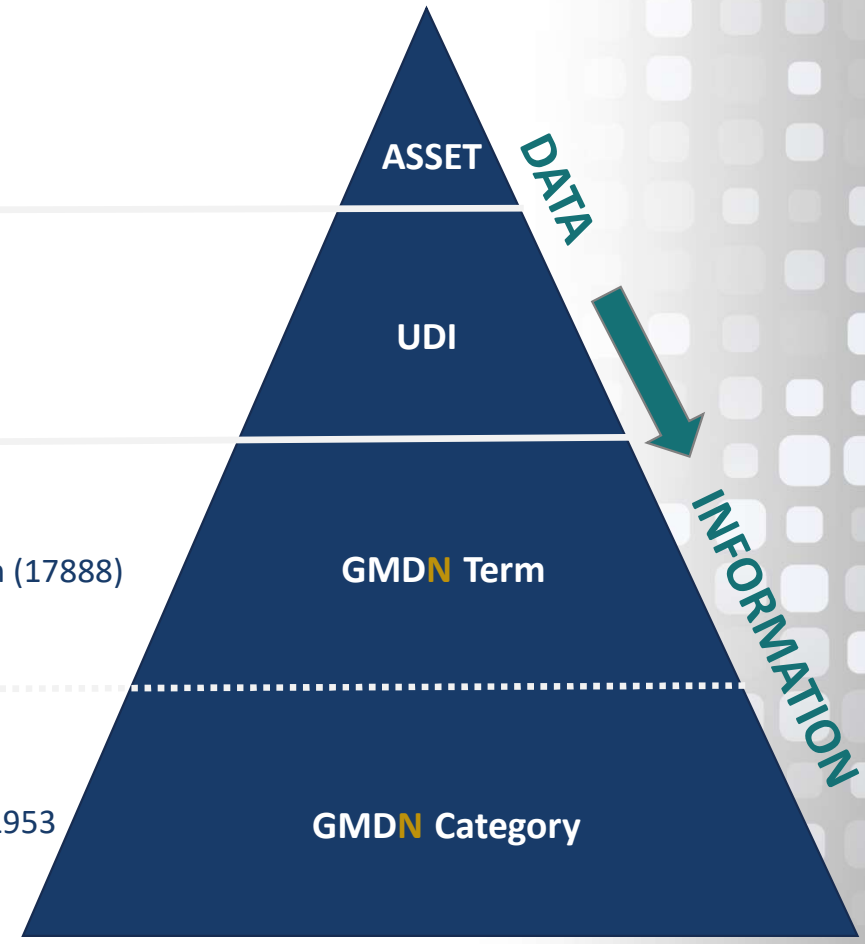
WHAT DOES A MEDICAL DEVICE NOMENCLATURE DO?

Asset code: ABC123

GTIN 12345678909874

Infrared patient thermometer, skin (17888)

Patient thermometers CT1953



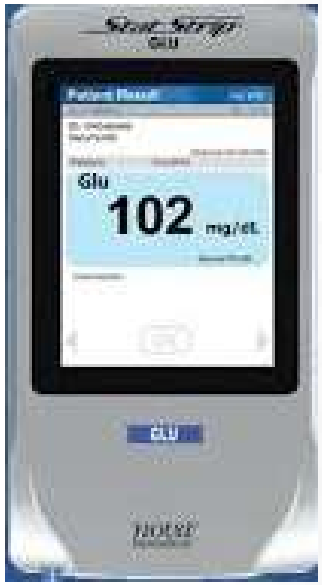
DATA ANALYSIS POSSIBILITIES USING GMDN

- Search examples:
  - Find me all the drug-eluting stents on the market. Now find me all the drug-eluting implants on the market.
  - This implant has been recalled. How many similar devices from other manufacturers are in patients?
  - How many Ventilators are there in the hospital?
- Analysis:
  - Is there a higher-than-expected incident rate for this manufacturer's implant compared with others on the market?
  - Is there a generic device problem, or is it just this manufacturer's device?
  - Is this device innovative? How does its performance compare with related devices?
- Enabling Interoperability:
  - Do these devices have a similar intended purpose?
  - Do these devices have similar form, features, or functions?
  - Enabling analysis when information is shared across different jurisdictions. E.g. information exchange between the MHRA-FDA-TGA-ANVISA-Health Canada-INVIMA-The WHO-, etc.

*Device substitutions should be decided by the HCPs. None of the GMDN content constitutes any endorsement, advice, representation or warranty about any specific medical devices that may be described by such content; and no representation or warranty is made in relation to instructions for use, suitability for any application, treatment or condition, regulatory status, or any properties of a particular medical device.

HOW TO NAME AND GROUP A MEDICAL DEVICE

EXAMPLE



GMDN CATEGORIES

- Device Function
  - CT954 In vitro diagnostic devices (IVDs)
    - CT943 Instrument/Analyser IVDs
      - CT840 Analyser IVDs
        - CT530 Clinical chemistry analyser IVDs
          - CT1918 Glucose analyser IVDs
  - Names Index
    - CT242 Analysers/Analysis systems and associated devices
      - CT1632 Analysers/Analysis systems
        - CT840 Analyser IVDs
          - Clinical chemistry analyser IVDs
            - CT1918 Glucose analyser IVDs
- Power
  - CT2985 Active
    - CT314 Electrically-powered
- Featured Attributes
  - CT2190 Glucose-measuring
  - CT331 Portable/Transportable

GMDN TERMS

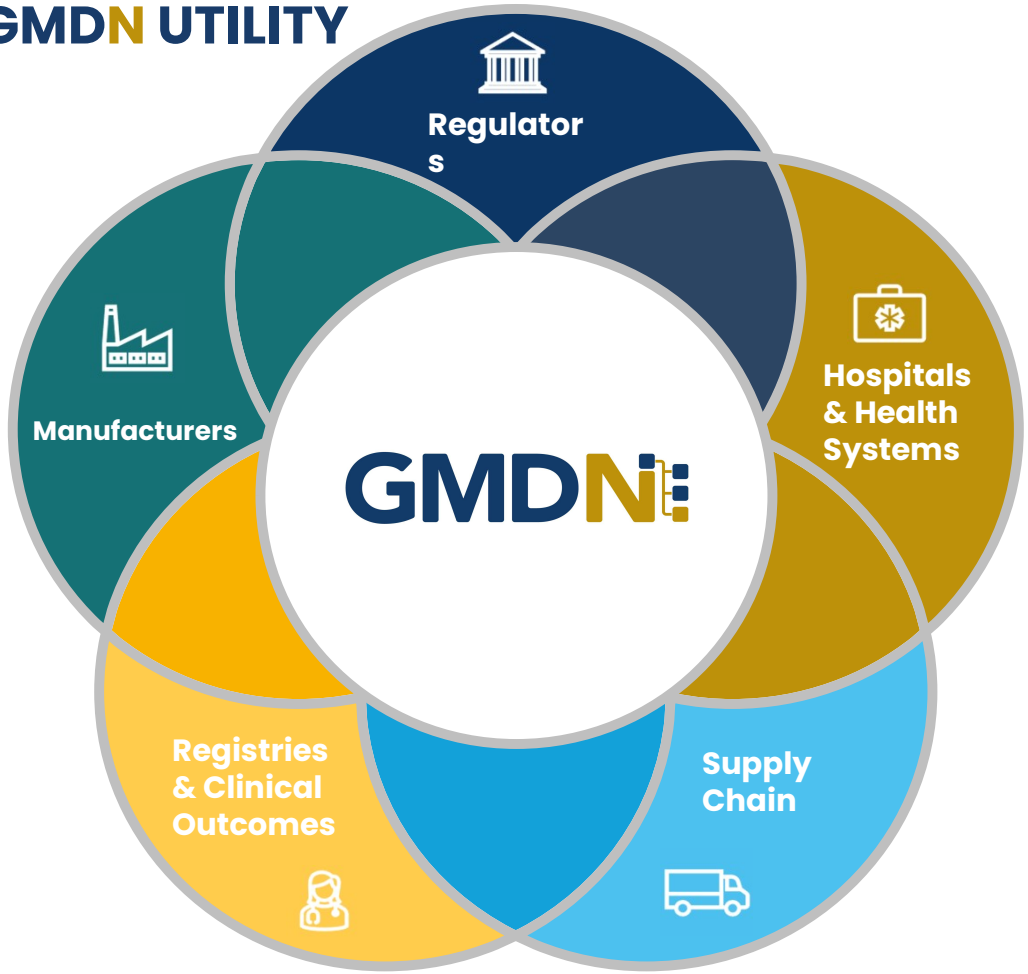
EXAMPLE

Glucose analyser IVD, point-of-care
62646
An electrically-powered instrument intended to be used exclusively at the point-of-care by medical professionals for the quantitative in vitro measurement of glucose levels in whole blood. Measured glucose values are used to manage blood glucose levels, primarily by persons with diabetes mellitus. This analyser is typically included in a blood glucose monitoring system.

CT1918 Glucose analyser IVDs

Name	Code	Status		
Glucose analyser IVD, home-use	62645	Active	CT	Details
Glucose analyser IVD, laboratory, automated/semi-automated	56686	Active	CT	Details
Glucose analyser IVD, laboratory, manual	62739	Active	CT	Details
Glucose analyser IVD, point-of-care	62646	Active	CT	Details
Glucose monitoring system IVD, home-use	62537	Active	CT	Details
Glucose monitoring system IVD, point-of-care	62538	Active	CT	Details

GMDN UTILITY



Regulators:
- Unique Device Identification (UDI) programmes and regulatory Databases (FDA GUDID, MHRA, TGA, ANVISA, Health Canada, INVIMA, WHO/MeDevIS)
- Safety signal detection and vigilance
- Harmonisation of device nomenclature for regulatory submissions

Hospitals & Health Systems:
- Inventory management and purchasing (UK NHS Supply Chain)
- Market analysis and procurement (Strata USA, Discovery Health South Africa)
- Device traceability and safety monitoring

Supply Chain:
- Tendering and procurement (GHC Joint Procurement Portal)
- Inventory optimisation
- Device tracking and recall support

Manufacturers:
- Device classification and regulatory submissions
- Market access and product registration
- Data integrity and assignment of GMDN Terms for product portfolios

Registries & Clinical Outcomes:
- National and international device registries (Netherlands National Implant Registry, USA FDA GUDID, UK NHS National Wound Care Project)
- Real-world evidence and post-market surveillance
- Data analysis for clinical outcomes and device performance

Medicines & Healthcare products Regulatory Agency

Government response

MHRA consultation on statutory fees: proposals on ongoing cost recovery

Published 2 September 2025

https://www.gov.uk/government/consultations/mhra-consultation-on-statutory-fees-proposals-on-ongoing-cost-recovery

GMDN

GMDN Agency Ltd
Hampden House, Monument Park
Oxford, OX44 7RW, United Kingdom
+44 (0)1235 799 759 | www.gmdnagency.org

Disclaimer:
The guidance provided by the GMDN Agency has been prepared in good faith and is intended to offer general information and assistance. However, it is important to note that any guidance or directives issued by the Medicines and Healthcare products Regulatory Agency (MHRA) take precedence over this document.

Identification of GMDN Level 2 Categories: A GMDN service for "Manufacturer Members" only

Starting the first week of October 2025, GMDN members with a **Manufacturers membership** will be able to:

- **Submit a list of GMDN Term Codes** associated with their devices to the GMDN Agency, for which they want to know the Device Function Category details.
- The GMDN Agency will then return the corresponding **Device Function Category Codes and Names** — either **Level 2 (L2)** or **Level 1 (L1)** — for each **GMDN Term**

This service will support improved classification, regulatory alignment, and data consistency across the UK medical device landscape.

https://www.gmdnagency.org/new-service-launched-for-gmdn-manufacturer-members-identification-of-gmdn-level-2-categories/

- Assigning the correct GMDN Term to each of your devices remains critical. We recommend incorporating a regular review of GMDN Term assignments into your quality processes to ensure accuracy and compliance.

- Recognise the wider impact of GMDN data: GMDN data is increasingly used by stakeholders across the NHS and beyond, particularly for procurement purposes. Inaccurate assignment may not only affect compliance but could also result in lost opportunities.
  - MHRA Database
  - PIM
  - NHS Supply Chain, NETIS
  - NHS Innovator Passport and MedTech Compass

"Whole NHS System Collaboration" as part of a "New MedTech Commercial and Growth Strategy"

GMDN SERVICES: EVOLVING WITH USER FEEDBACK

User Support

- Advanced Search
- Enquiry service
- Look up service (EMDN) – Manufacturers
- My Terms (Account specific Term management)
- My Categories (Account specific Category management)
- Custom Categories for Regulators and Healthcare Providers
- Multiple Account Users
- Translations (Multi-Language)
- New: Identification of GMDN Level 2 Categories: A GMDN service for "Manufacturer Members"

Communicating with GMDN

- Notifications:
  - Term obsoletions & replacement term support
  - Term amendments
  - Monthly account summary
- Workshops/trainings/1-2-1 sessions
- Monthly newsletters
- Agile "User Support"
- Annual stakeholders survey and interviews

Implementation Support

Experience, >13 years compulsory requirement UDI

- Implementation assistance:
  - Regulatory including UDI
  - Health service
  - Supply chain
- Data analysis assistance:
  - Regulatory
  - Health service
  - Supply chain
- Term assignment support

Governance
Technical Advisory Group (TAG) Meetings
Authorities Strategic Advisory Group (ASAG) Meetings

Nomenclature Development
Driven by industry/innovation
Opportunity to provide feedback on the Database in real-time

KEY TAKEAWAYS FOR MEDICAL DEVICE MANUFACTURERS

Why is GMDN IMPORTANT TO YOU?

- Pre-market approval
- Supply Chain Management
- Hospital Operation
- Post-market surveillance

How does GMDN HELP YOU?

- Common Language
- Traceability
- Interoperability

- Accurate GMDN Term assignment is the key
  - Each device (packaged separately) should be assigned to a single GMDN Term that represents the device with accuracy
- Manufacturer's "Medical Device Database QMS" should cover all UDI programme components, including GMDN, reviewing and updating your GMDN Term assignments

Thank you

https://www.gmdnagency.org/contact-us/

https://www.gmdnagency.org/training/

https://www.gmdnagency.org/case-studies/

GMDN