

INTRODUCTION

29TH GHWP ANNUAL MEETING AND 29TH GHWP TECHNICAL COMMITTEE MEETING IN BANGKOK 1-4 DECEMBER 2025

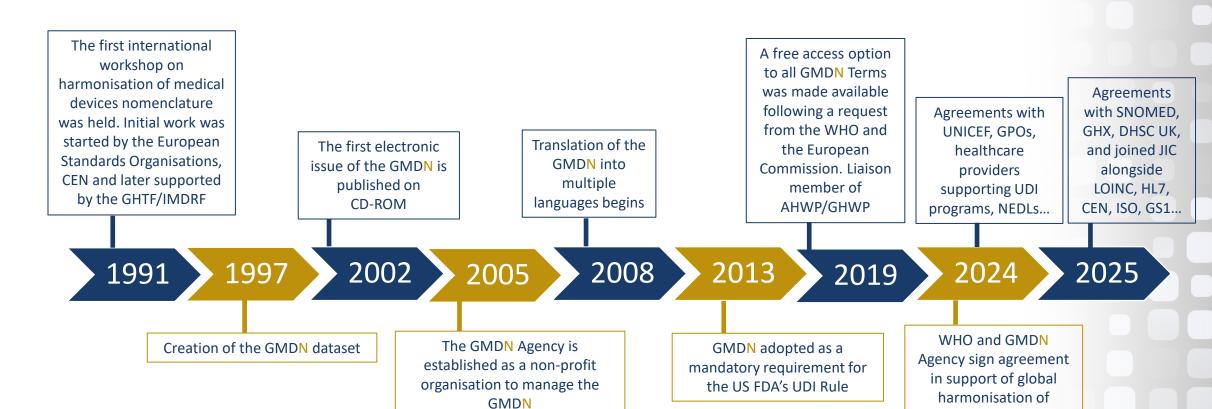
DENIZ BRUCE - CEO

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



THE GMDN HISTORY

A NON-PROFIT, CHARITY*





medical device nomenclatures

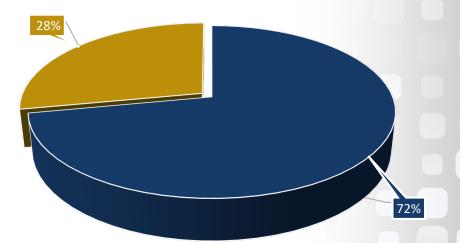
^{*} https://register-of-charities.charitycommission.gov.uk/en/charity-search/-/results/page/1/delta/20/keywords/GMDN

WHAT WE DO GLOBAL MEDICAL DEVICE NOMENCLATURE (GMDN)

A NON-PROFIT, CHARITY (#1154418)

- >30 years of experience in nomenclature development and maintenance
- >12 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, Healthcare Providers. Membership options (incl. free of charge) are available: https://www.gmdnagency.org

GMDN Use in 139 of 194 Countries*



- Countries with GMDN Access/Members
- Countries without GMDN Access/Members

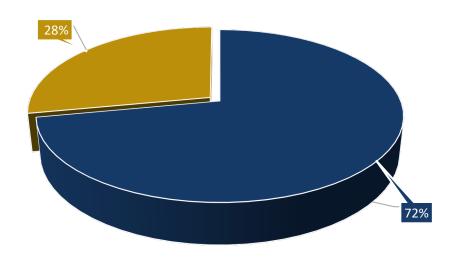
*Nov 2025: Registration/membership info is in real-time.

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 ACROSS THE WORLD

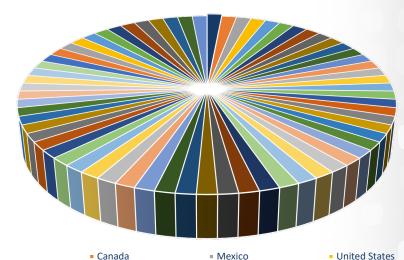
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GMDN Use By Regulators/Government **Departments***



- EU
- Argentina
- Cuba
- Honduras
- Botswana
- Kenya
- South Africa
- Azerbaijan
- Iran
- Kyrgyzstan
- United Kingdom
- New Zealand
- Thailand
- Uzbekistan
- Lebanon
- Somalia
- Tunisia
- Norway
- Eritrea
- Libya

- Mexico
- Ecuador
- Peru

Brazil

- Egypt
- Mozambique
- Tanzania
- Bahrain
- Japan
- Malaysia Ukraine
- Bosnia and Herzegovina
- Vietnam
- EEU

- Chile
- El Salvador
- Uruguay
- Ethiopia
- Nigeria
- Uganda
- Bangladesh
- Kazakhstan
- Mongolia
- Turkey

South Korea

Mordovia

Iceland

Sudan

Pakistan

Philippines

- Australia
 - Oman
 - South Africa

Colombia

Guyana Burkina Faso

Ghana

Rwanda

Armenia

Bhutan

Kuwait Switzerland

- India
- Russia
- Yemen



WHAT DOES A MEDICAL DEVICE NOMENCLATURE DO?



Asset code: ABC123



GTIN 12345678909874



Infrared patient thermometer, skin (17888)



ASSET

UDI



Patient thermometers CT1953

GMDN Category

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



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











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

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

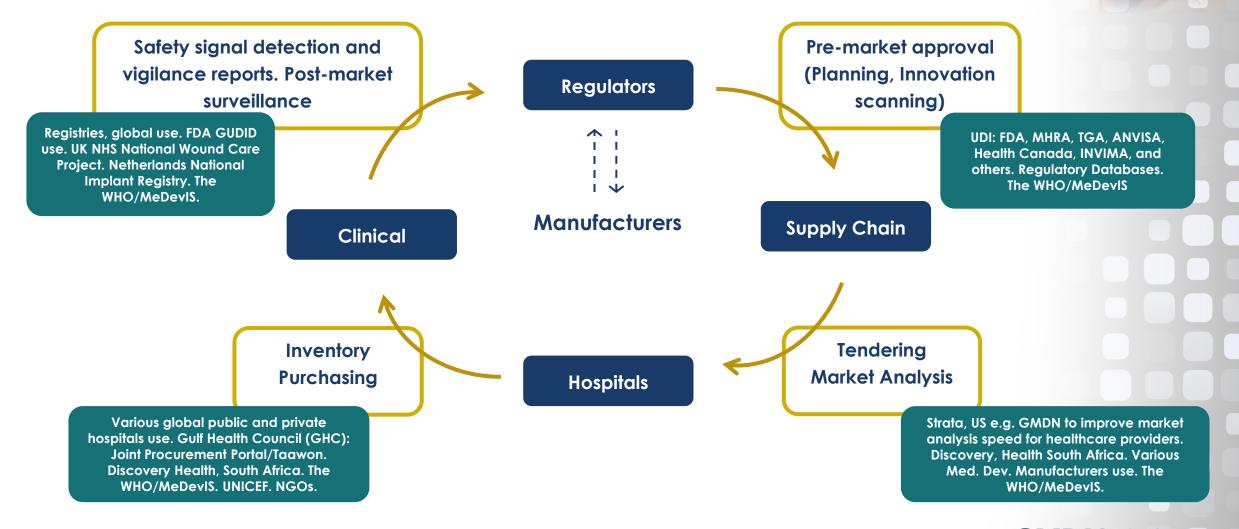
Name	Code	Status		
Glucose analyser IVD, home-use	62645	Active	CT	<u>Details</u>
Glucose analyser IVD, laboratory, automated/semi- automated	56686	Active	<u>CT</u>	<u>Details</u>
Glucose analyser IVD, laboratory, manual	62739	Active	<u>CT</u>	<u>Details</u>
Glucose analyser IVD, point-of-care	62646	Active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



GMDN USE-CASES

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





GMDN SERVICES: EVOLVING WITH USER FEEDBACK

ANNUAL SURVEY: HTTPS://US1.LIST-MANAGE.COM/SURVEY?U=8608000A9D83AED5A46919D86&ID=E9CB560AEA&ATTRIBUTION=FALSE



User Support

- Advanced Search
- Enquiry service
- Look up service 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)

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, >12 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



Thank you

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

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

