ENABLING GLOBAL HARMONISATION OF MEDICAL DEVICE IDENTIFICATION

A GLOBALLY TRUSTED NOMENCLATURE SUPPORTING REGULATORY INTEROPERABILITY AND UDI SYSTEMS.

Confidential – Do not duplicate or distribute without written permission from GMDN Agency.

One Term. One Device Type.

GMDN is a flat listing of 25,000+ mutually exclusive generic device descriptors. One GMDN Term per device type, regardless of manufacturer, brand name or country of origin.

25,000+ medical device Terms — one per device type

Each Term has a unique 5-digit GMDN Code and a name and a definition

Terms sit within a multi-level category hierarchy of 2,600+ categories

153
countries with GMDN members

1 GMDN Term
covers all equivalent devices from all manufacturers globally

GMDN AT A GLANCE

- **5M+** medical device identifier records registered within UDI databases.
- **13,000+ GMDN** members across 153 countries
- **107** countries with regulators registered or using GMDN in some regulatory capacity
- **Updated in real-time** to keep pace with device innovation — Terms added as new device types emerge

GMDN is a shared language that enables regulators, manufacturers, healthcare providers and other stakeholders to communicate clearly and consistently about medical devices.

Confidential – Do not duplicate or distribute without written permission from GMDN Agency.

Data Structure

Traditional classification locks devices into fixed hierarchical buckets which are rigid, slow to update, and inconsistent across jurisdictions. GMDN takes a different approach: functional definitions that travel with the device, not specific to the regulator.

GMDN CATEGORIES multi-hierarchical grouping — 2,626 Categories

- Device Function
  - Tissue reparation devices CT1007
    - Stents CT2090
      - Vascular Stents CT485
        - Coronary artery stents CT1102

Example path shown – Categories at 5 levels

…and many more Categories for other device types

GMDN Terms flat listing of Terms — 25,454 Terms

Antibody-coated-metal coronary artery stent	47826
Bare metal coronary artery stent	53616
Bioabsorbable coronary artery stent	61535
Drug-coated-metal coronary artery stent	62301
Drug-eluting coronary artery stent, antibody-coated	58760
Drug-eluting coronary artery stent, carbon-coated	56285

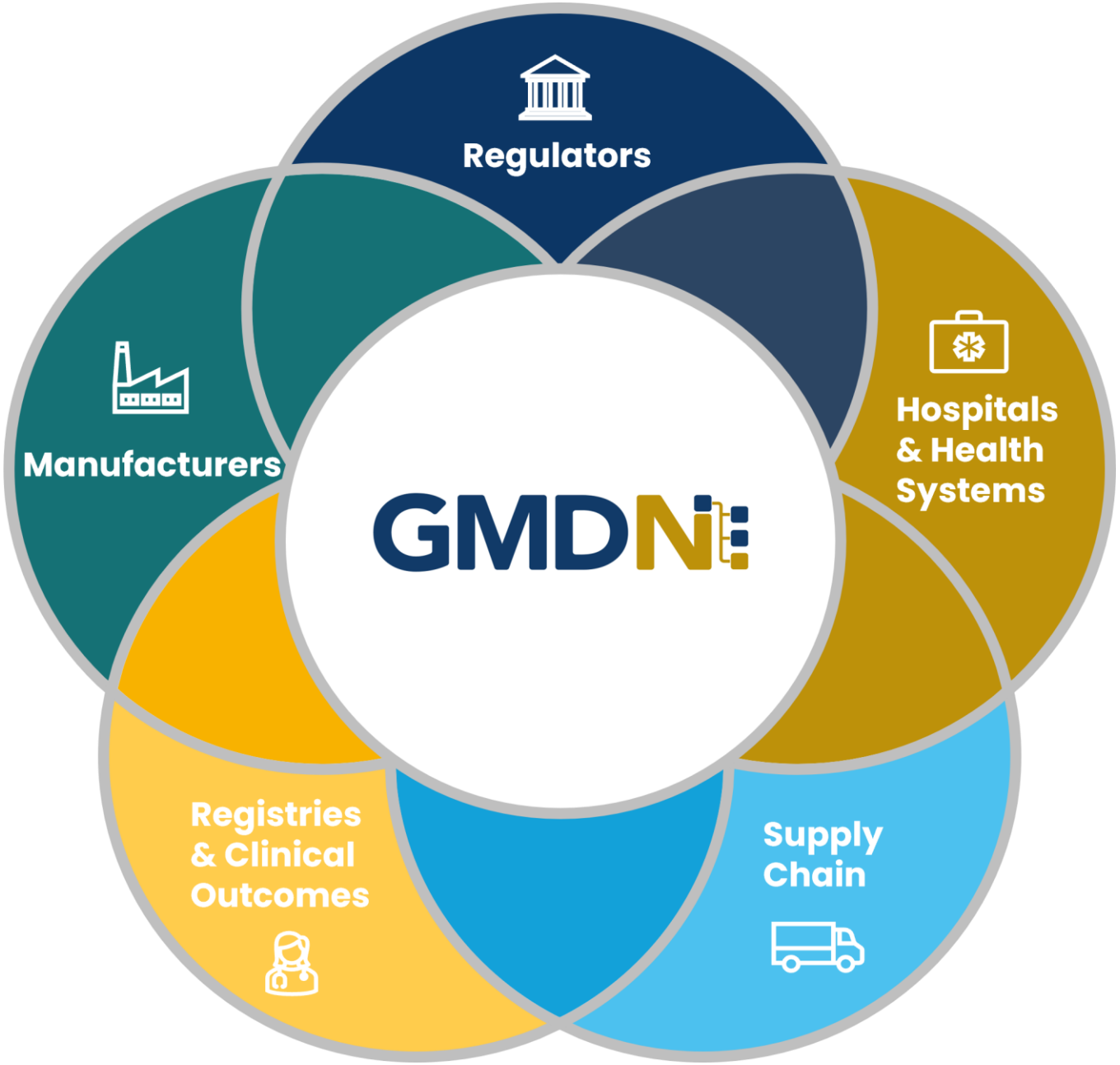
25,000+
GMDN Terms

5M+
Devices with GMDN in UDI Databases

107
Countries using GMDN in a regulatory capacity

One device type = One GMDN Term
Regardless of manufacturer, brand name or country of origin giving regulators a single source of truth

Confidential – Do not duplicate or distribute without written permission from GMDN Agency.



The Same Code. Across the Entire Ecosystem.

Once a GMDN Code enters a registration system, it doesn't stay there. The same GMDN Term travels through procurement, clinical use, post-market surveillance, inventory management and registries, connecting data that was previously siloed.

One Product, One Term - Only assign a single Term to your product. All GMDN Terms are mutually exclusive. Multipurpose devices should be assigned to a Term describing a multipurpose device. Kits should be assigned to the appropriate kit Term. For implants, a set containing the implant is typically covered by the Term describing the implant. The definitions will indicate this.

Accurate Product Representation – Make sure the GMDN Term name and definition accurately represent your device. If key intended uses of your device are not mentioned in the definition, it may not be the appropriate Term.

Be Component Specific – A component of a system should be assigned to a Term that describes that component, not assigned to the Term for the overall system. Likewise, a component/accessory of a parent device should be assigned to a Term that describes that component/accessory, not assigned to the Term for the Parent device.

Confidential – Do not duplicate or distribute without written permission from GMDN Agency.

Use Case 1: Post-Market Surveillance & Recalls

The most immediate benefit for regulators beyond registration. GMDN makes post-market surveillance systematic rather than manual and makes recalls instant rather than sequential.

WITHOUT A SHARED NOMENCLATURE

Safety notification arrives
Notice linked to a specific brand and model. Regulator must identify all equivalent devices from other manufacturers

Manual matching
Each manufacturer registered under different names. Equivalent devices in other markets may be invisible without a shared identifier

Other markets informed
Regulators in other jurisdictions rely on manufacturer notifications. No independent mechanism to identify affected devices in their market

Recall Issued
Delayed action. By the time affected devices are identified across all markets, harm may already have occurred

THE GMDN DIFFERENCE

Real-time solution

A safety notice arrives linked to a specific brand and model.

Without GMDN, a regulator must manually identify every equivalent device from every other manufacturer, a process that takes valuable time and relies on manufacturer cooperation across borders.

With GMDN, that same notice, linked to a single Code, **automatically captures every equivalent device across all manufacturers and all markets.** No manual reconciliation. No missed devices. No delay.

Cross-border surveillance
Safety signals linked to a GMDN Code **are immediately visible to every regulator using GMDN. No bilateral communication required.**

Instant recall scope
A recall tied to a GMDN Code **captures every equivalent device from every manufacturer** across all markets, instantly.

No brand-name reconciliation
One GMDN Code identifies all equivalent devices regardless of what manufacturers call them. N**o manual matching across registrations.**

Horizon scanning
Monitor device-type level patterns across all manufacturer, identifying emerging safety concerns **before they become formal reports.**

One Code. Every equivalent device. Instantly. When a recall is tied to a GMDN Code, it a common device language across all manufacturers and all markets instantly. No manual reconciliation, no missed devices, no delay.

Confidential – Do not duplicate or distribute without written permission from GMDN Agency.

Use Case 2: Hospitals and Healthcare Systems

The same Code manufacturers assign for regulatory compliance is already being used by hospitals to standardise procurement, compare device costs and manage inventory at no additional burden to anyone in the supply chain.

MANUFACTURER

- Device registered with regulator with GMDN Code.
- Leaves factory with a UDI label, GMDN embedded into DI component

HOSPITAL PROCUREMENT

- Hospital used GMDN to categorise products for purchase, managing device inventory and asset management

CLINICAL OUTCOMES

- Device outcome data collected by device registries with GMDN used to compare performance of like devices.

GMDN CODE

- Major regulators across the world already mandate the use of GMDN for registration
- Every device on the market carried a GMDN Code
- No new nomenclature-related data collected manually by suppliers

- Catalogues can be standardised using a common language, GMDN
- Benchmark equivalent devices across brands and tenders
- Manage inventory and respond to recalls; extend
- No new nomenclature-related data collected manually by suppliers

- GMDN is the device component of SNOMED CT, connecting procurement to clinical records
- Device data at the point of care can be traced back to original registration
- Regulators could receive safety notices from clinical systems, closing the loop.

NHS Supply Chain, UK Active

NHS Supply Chain uses GMDN as a recognised data standard to standardise device cataloguing and procurement across the NHS

Discovery Health, South Africa Active

Discovery Health, an insurance company, uses GMDN for risk and cost management, and benchmarking

Gulf Health Council, GCC Countries Active

GHC Joint Procurement Portal uses GMDN for tendering, inventory optimisation and device tracking

Strata, USA Active

Strata USA uses GMDN for market analysis and procurement intelligence across health systems

Confidential – Do not duplicate or distribute without written permission from GMDN Agency.

Use Case 3: Registries & Clinical Outcomes

GMDN is the identifier that turns registry data into regulatory intelligence, connecting device-type performance across manufacturers, markets and clinical settings.

REGISTRIES USING GMDN

NHS

United Kingdom

National Wound Care Project

- Used as the basis for a new wound product classification system, aligning groupings of wound management products to high-level GMDN codes, then adding further clinical differentiation.
- Enabled consistent naming, coding and grouping of products across data from MHRA, the Drug Tariff and NHS Supply Chain, drawing on data from multiple sources in a standardised way

LIR

Netherlands

Dutch Implant Registry

- GMDN used in the Dutch National Implant Registry to enable consistent identification of every registered implant
- Allows the Health and Youth Care Inspectorate (IGJ) to rapidly identify affected implants and trace patients in the event of a safety issue or recall

WHAT THIS MEANS FOR REGULATORS

Registry data linked to GMDN allows regulators to ask a fundamentally different question: **how are all devices of this type performing across all manufacturers?**

This is only possible with a shared device identifier. Regulators using GMDN can receive real-world evidence directly from registries without any reconciliation, supporting **benefit-risk assessment, horizon scanning and post-market decision-making at the device-type level.**

Device-type surveillance
Ask how all devices of this type are performing across all manufacturers

Horizon scanning
Identify emerging safety signals before they become formal reports

Benefit-risk assessment
Assess benefit and risk at device-type level, not just a single submission

Cross-border comparability
Registry data linked to GMDN is comparable across borders, enabling international evidence sharing

One code. Every device type. Globally. When a regulator uses GMDN, registry data from any country using the same code becomes directly comparable, No reconciliation, no translation, no delay.

The Regulator's Role in Data Quality

GMDN is only as powerful as the accuracy of the assignments behind it. Regulators are uniquely positioned and uniquely responsible for ensuring Term assignment accuracy.

Registration is the point of entry. It is also the only point in the device lifecycle where a regulator has the authority to mandate that a GMDN Code is **correct, not just present.**

THE PROBLEM WITH UNVERIFIED ASSIGNMENTS

Manufacturers assign GMDN Codes at the point of registration.

Without a quality checking mechanism, Codes can be **plausible but incorrect**, and a device registered under the wrong Term looks compliant but carries the wrong identity through every downstream system that depends on it.

WHAT FLOWS DOWNSTREAM FROM REGISTRATION

- **Recalls —** An incorrect Code means equivalent devices are missed when a safety notice is issued
- **Registries —** Outcome data grouped by device type. Incorrect Codes mean wrong groupings, undermining clinical evidence
- **Procurement & inventory —** Hospitals use GMDN to compare and standardise devices. Incorrect Codes break that comparability
- **Post-market surveillance —** Safety signals only capture devices correctly coded under the relevant Term

ONLY REGULATORS CAN MANDATE ACCURACY

- Manufacturers have commercial incentives and varying levels of expertise in GMDN assignment
- Health systems and registries consume the data but cannot correct it at source
- Only the regulator, at the point of registration or UDI submission, has both the authority and the mechanism to require verified, consistent and maintained GMDN assignments
- Manufacturers should be able to update and correct their registration records, should they be made aware of an incorrect assignment

Data quality at registration is a patient safety decision, and only regulators have the mandate and authority to enforce it.

The Ask Is Smaller Than the Return

Mandating or adopting GMDN for registration is a single decision. The return across surveillance, recalls, procurement alignment and real-world evidence compounds across every other system that uses the same Code.

1

If you already mandate GMDN

Engage with the GMDN Agency to ensure your database integration is current, your team can access the full category hierarchy. You can also have access to regular automated updates via FTP.

→ **communications@gmdnagency.org**

2

If you are building a UDI framework

GMDN is the WHO-endorsed nomenclature standard, adopted by every major IMDRF-aligned system. It is ready to adopt without building from scratch — and the infrastructure investment pays dividends across the entire device lifecycle.

→ **gmdnagency.org/register**

3

If you want to go further

Join the GMDN technical advisory process. Regulators who participate help shape how emerging device categories are defined — ensuring the standard reflects real-world oversight needs as device technology evolves.

→ **Sign up for the Technical Advisory Group**

GMDN

Ready to talk? communications@gmdnagency.org | gmdnagency.org