# GET MORE FROM YOUR GMDN MEMBERSHIP

**HOW PAID MEMBERSHIP REMOVES FRICTION FROM REGULATORY SUBMISSIONS, MARKET ACCESS AND PRODUCT PORTFOLIO MANAGEMENT.**

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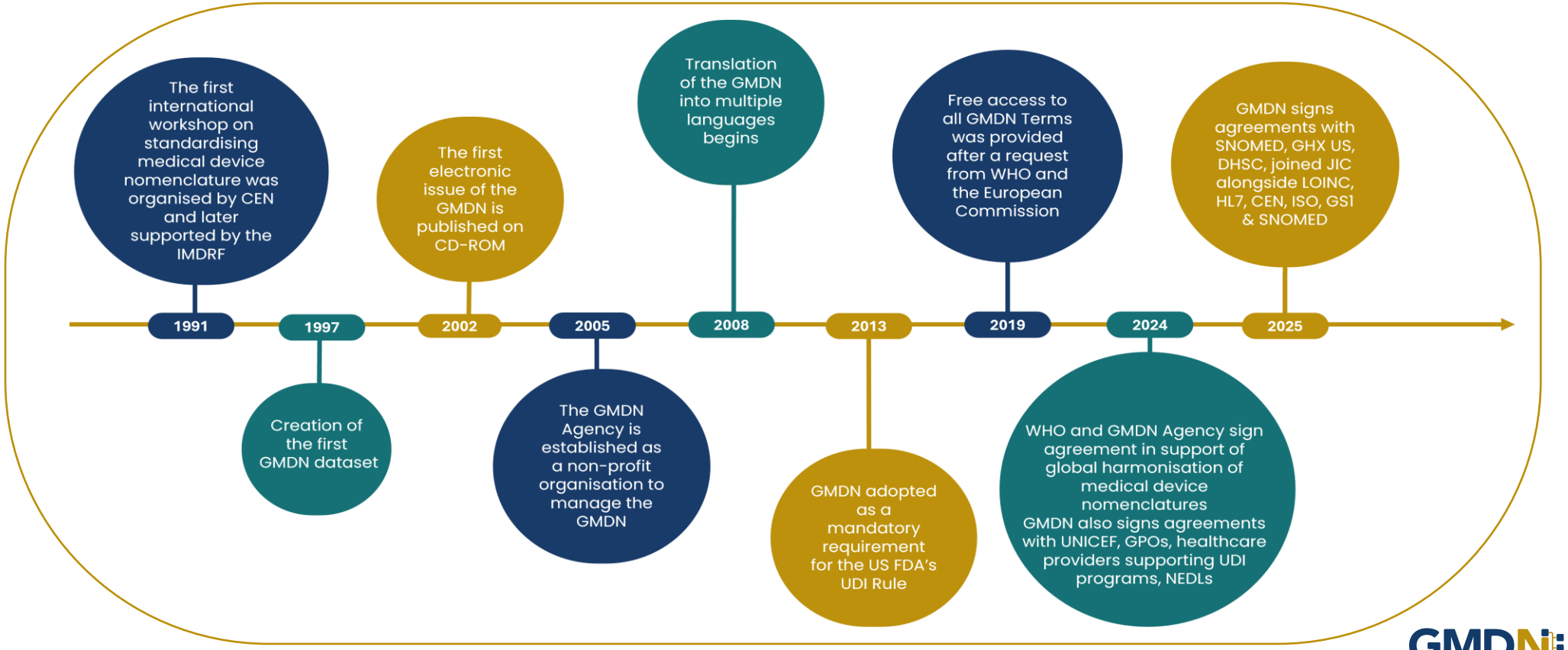
# What is the GMDN?

The Global Medical Device Nomenclature (GMDN) is the world's foremost standard for naming, defining, and categorising medical devices. The system provides a global common language that enables regulators, manufacturers, healthcare providers, and other stakeholders to communicate clearly and consistently about medical devices.

GMDN uses internationally agreed generic descriptors to identify medical devices by intended use, technology/material, form/components, and significant attributes. The GMDN Database is continuously updated with new Terms to capture innovative technologies. The GMDN is managed by the GMDN Agency, a registered charity, which has a Board of Trustees representing regulators, industry and healthcare providers.



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# GMD 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 the system.

**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

**106**
Countries using GMDN in a regulatory capacity

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

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# IVD Data Structure

The GMDN offers a shared global language, and for IVDs, one that covers a complex and critical product area. Getting the structure right matters for regulators who rely on the data, and for the manufacturers require to use it

**GMDN IVD CATEGORIES** multi-hierarchical grouping 860 Categories

- Device Function
  - In vitro diagnostic medical devices (IVDs) CT954
    - Analyte assay IVDs CT350
      - Clinical chemistry IVDs CT287
        - Clinical chemistry hormone IVDs CT850

*Example path shown – Categories at 5 levels*

…and many more Categories for other analytes, instruments and consumables and software.

**GMDN IVD Terms** flat listing of Terms 13,860 Terms

| | |
|---|---|
| 17-Hydroxyprogesterone IVD, calibrator | 45708 |
| 17-Hydroxyprogesterone IVD, kit, control | 45709 |
| 17-Hydroxyprogesterone IVD, kit, chemiluminescent immunoassay | 58346 |
| 17-Hydroxyprogesterone IVD, kit, enzyme immunoassay (EIA) | 63577 |
| 17-Hydroxyprogesterone IVD, kit, fluorescent immunoassay | 61469 |
| 17-Hydroxyprogesterone IVD, kit, radioimmunoassay | 54043 |
| 17-Hydroxyprogesterone IVD, kit, spectrophotometry | 54042 |
| 17-Hydroxyprogesterone IVD, reagent | 54044 |

**Analyte IVD, [component], [methodology]***

*for kits only

# 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 manufacturers, regulators, healthcare providers and other stakeholders to communicate clearly and consistently about medical devices.**

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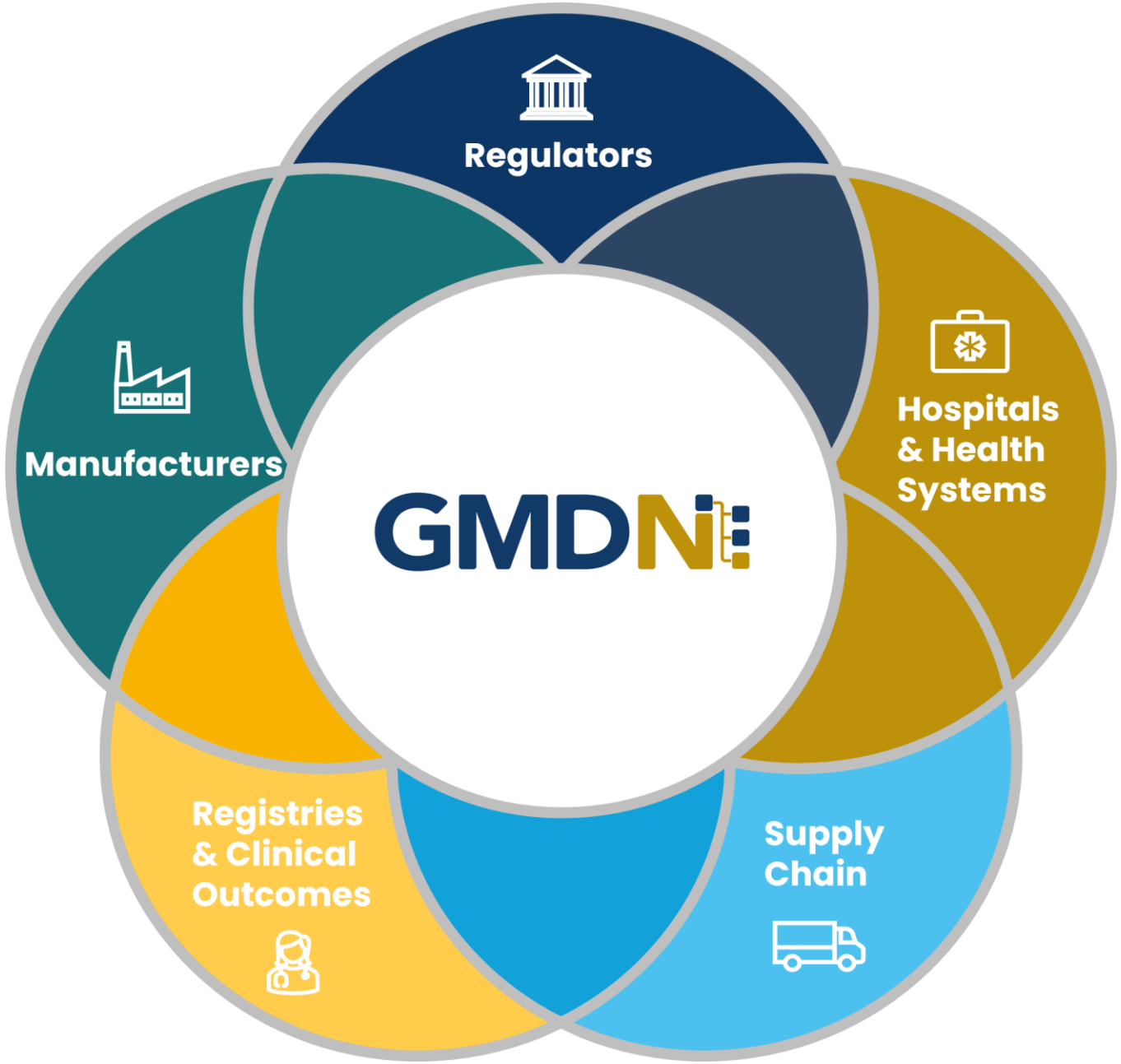


# The Same Code. Across the Entire Ecosystem.

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.



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# The Manufacturers Role in Data Quality

GMDN is only as powerful as the accuracy of the Term assignments behind it. It is vital that GMDN Term assignment accuracy is correct at point of entry.

**Registration is the point of entry.** It is the most important point in the device lifecycle where a GMDN Code is **correct, not just present.**

## IMPORTANCE OF CORRECT ASSIGNMENT

Manufacturers assign GMDN Codes at the point of registration.

Codes can be **plausible but incorrect**, and a device registered under the wrong GMDN 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

## ACCURACY IS KEY

- Manufacturers have commercial incentives to ensure correct 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 update and correct their registration records, should they be made aware of an incorrect assignment

**Data quality at registration can affect patient safety, clinical outcomes and procurement outcomes for manufacturers.**

# Use Case: Procurement

The same GMDN 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 carries 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



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# Paid membership benefits for Manufacturers

**Operational efficiency & scale:** Paid membership streamlines management of your device portfolio by letting you organise and monitor the GMDN Terms and GMDN Categories you rely on, with tools such as Advanced Search, My Terms and My Categories and alerts that reduce manual effort and rework as the nomenclature evolves.

**Multi-user access:** These GMDN membership types benefit from having the ability to have multiple account users. Useful if your organisation is large or geographically distant.

**Regulatory readiness:** Using the GMDN supports regulatory submissions, post-market surveillance, and market access. reduces classification errors and supports smoother interactions with regulators across jurisdictions.

**Data governance & quality:** GMDN use can help drive cleaner internal data and better alignment across resource planning, quality, vigilance, and UDI processes—improving traceability and downstream analytics.

**Time-saving notifications:** Optional notifications keep you ahead of changes to relevant Terms, helping teams maintain accuracy without constant manual checks.

**Extra support:** We offer training workshops delivered by our expert team to ensure you are using the GMDN to the best of your ability and meeting your needs.

**EMDN:** Our nomenclature assignment service to assist you in finding the appropriate European Medical Device Nomenclature (EMDN) codes for your devices based on your existing GMDN Code.



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# Further information

1

## If you are already a GMDN member

Engage with the GMDN Agency to help with your account management.

→ admin@gmdnagency.org

2

## If you need training

We have training resources, videos and user guides for GMDN members. If you need training for your organisation, please contact us

→ www.gmdnagency.org/training

3

## Connect with us

To receive GMDN updates you can activate GMDN updates within your account. You can also follow us on LinkedIn for news and insights.

→ www.linkedin.com

GMDN

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