GMDN

A standardised nomenclature is essential for maintaining patient safety and promoting better healthcare outcomes

STRATEGY 2026 – 2030

INTRODUCTION

JOHN WILKINSON

CHAIR OF THE BOARD OF TRUSTEES

"The coming years represent a period of rapid technological evolution for the Global Medical Device Nomenclature (GMDN) Agency.

As Chair of the Board of Trustees, I am honoured to present this strategic plan, shaped by thoughtful discussion and a shared

commitment to global health. GMDN stands as the world's leading standard for medical

device nomenclature, trusted in over 140 countries, and its success is rooted in our unwavering focus on patient safety, regulatory excellence, and international collaboration.

Our Board of Trustees— representing regulators, healthcare providers, and industry —brings diverse expertise and perspective to our governance. This new strategy reflects our proactive approach to addressing the challenges of device innovation and evolving regulations.

At the heart of our mission is the expertly curated, dynamic GMDN data set. This expert curation is a unique strength that none of our challengers can match, and it complements our independence and trusted integrity.

Linked to this is the critical issue of 'master data'—where quality and cost are paramount. Multiple systems not only require significant resources to establish and maintain but also compromise utility. GMDN provides all users with a single version of the truth, delivering high -quality data at low or no cost.

Oversight by the GMDN Agency Board, along with guidance from our Technical Advisory Group (TAG) and Authorities Strategic Advisory Group (ASAG), keeps GMDN relevant and harmonised globally. Looking ahead to 2030, our priorities are clear: strengthen GMDN's leadership, enhance stakeholder engagement, invest in our data platform, and future-proof our organisation. We will continue building partnerships with international bodies and expand into new jurisdictions, while maintaining free access for regulators and healthcare providers through a sustainable funding model.

Above all, we remain dedicated to our mission of providing a unified language for medical technology worldwide to benefit patients and public health.

On behalf of the Board of Trustees, I thank our CEO, Deniz Bruce, our GMDN Agency team, and our global community for their commitment. Together, we will continue to set the standard for medical device nomenclature, supporting innovation, safety, and collaboration across healthcare."

EXECUTIVE SUMMARY BY THE CEO

DENIZ BRUCE

CEO

"The GMDN Agency's 2026–2030 strategy is both a reaffirmation of our founding principles and a bold step forward.

As a non-profit charity, our mission is to protect patients by providing a globally harmonised, standardised nomenclature for medical devices.

Over the past three decades, GMDN has become an indispensable tool for regulators, manufacturers, and healthcare providers, underpinning regulatory compliance, market access, and patient safety.

This strategy is shaped by extensive stakeholder engagement, including Board workshops, advisory group consultations, and feedback from our international user base. We have listened carefully to the needs and aspirations of our community.

The result is a plan that prioritises global harmonisation, interoperability, and equitable access. We will invest in technology and talent, enhance our training and outreach, and continuously improve our services and governance.

Key priorities for the next five years include:

- Strengthening GMDN's position as the leading medical device nomenclature provider in the world.
- Expanding our partnerships with like-minded standard organisations and geographical representation to further support global harmonisation.
- Maximising stakeholder engagement through tailored communications, training and advisory groups.
- Investing in our Database and IT infrastructure to ensure future readiness.
- Maintaining a sustainable funding model that balances equitable access with the need for ongoing investment.

Our vision is ambitious but achievable: a single, common language for all medical technology, adopted by regulators, manufacturers, and healthcare systems worldwide.

Our values—leadership, collaboration, innovation, and integrity—will guide every action we take.

I am grateful to our Board of Trustees, our dedicated expert staff, and stakeholders for their unwavering support and commitment. Together, we will deliver on this strategy and continue to advance global health."

NAVIGATING COMPLEXITY: GMDN'S JOURNEY, GLOBAL HARMONISATION, AND THE AGE OF AI

The Global Medical Device Nomenclature (GMDN) was established in the early 1990s to address the growing need for a standardised, internationally recognised system for naming, defining and categorising all medical devices. Initiated by the European Standards Organisations and later supported by the Global Harmonisation Task Force (now the IMDRF), GMDN's development brought together regulators, manufacturers, and healthcare providers from around the world. Over the past three decades, the GMDN Agency—a non-profit, UK-registered charity—has overseen the evolution of this nomenclature, ensuring it remains current, comprehensive, and provides equitable access to stakeholders globally.

GMDN's adoption by regulatory authorities such as the US FDA, UK MHRA, Australian TGA, Brazilian ANVISA, Colombian INVIMA, Ethiopian EFDA, the FDA Ghana as well as many others, and its integration into the WHO's initiatives underscore its pivotal role in enhancing patient safety, streamlining regulatory processes, and facilitating international trade in medical devices. The nomenclature's dynamic structure allows it to adapt to technological innovation and new regulatory requirements, supporting a global community of users across more than 140 countries.

However, the pursuit of global harmonisation faces persistent challenges.

Political divergence—manifested in differing national regulations, priorities, and approaches—often impedes the establishment of unified standards. For example, while GMDN is widely recognised, some regions have developed alternative nomenclatures, leading to complexities in harmonisation and interoperability. These divergences can slow market access, increase compliance costs, and complicate international collaboration. (cont.)

The rapid advancement of artificial intelligence adds another layer of complexity. AI-driven tools are transforming regulatory science, supply chain management, and post-market surveillance.

Yet, the integration of AI also raises new challenges: ensuring algorithmic transparency, managing data governance, referring to and respecting the source data, respecting IPs and addressing potential biases—political or otherwise—that may be embedded in AI systems.

As AI becomes more influential in shaping regulatory decisions and harmonisation efforts, it is essential to maintain robust governance frameworks that reflect diverse perspectives and safeguard public trust.

In this environment, GMDN's mission remains clear: to provide a trusted, independent, and adaptable foundation for global medical device nomenclature.

Success will depend on proactive engagement with emerging technologies, ongoing dialogue among international stakeholders, and a commitment to bridging political and regulatory divides—even as the landscape grows more complex in the age of AI.

DENIZ BRUCE

CEO

GMDN CASE STUDY: US FDA UDI

The US FDA's UDI Database (Global UDI Database – GUDID) has over 4.5 million records for medical device products marketed in the US over the last 14 years. Every record is linked to a GMDN Term so that the entire dataset could be analysed by Category to find trends, signals etc. The most important grouping of devices found early on was to distinguish implantable devices, which have very different use, life and clinical significance to non-implantables.

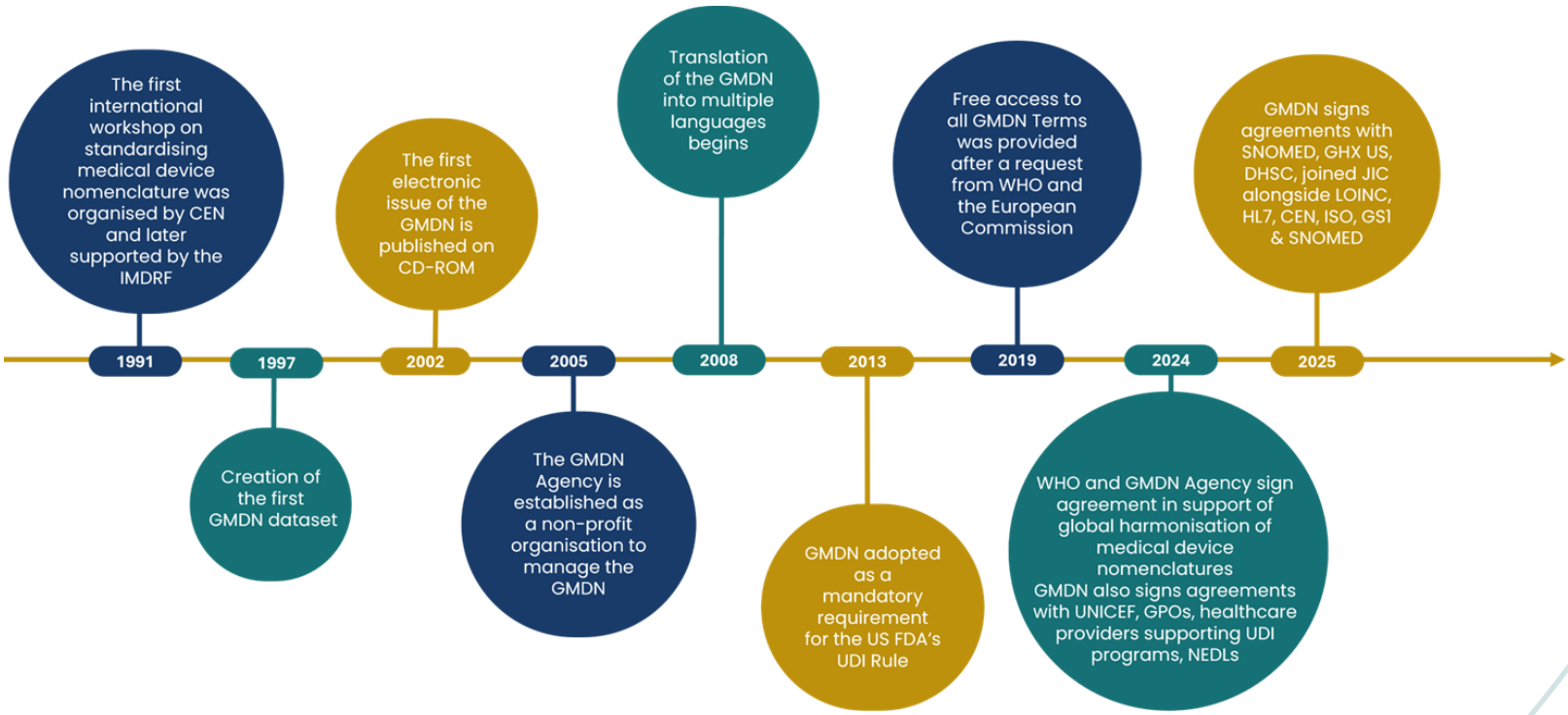
An analysis by a third-party showed conclusively that using the GMDN nomenclature and classification was the most accurate way to distinguish implantables, which was then adopted by the FDA. The implantables grouping on the AccessGUDID uses the GMDN Category for implantables to group the GMDN Terms and therefore products and the FDA takes a regular download from the GMDN Agency to do that grouping.

HISTORY OF THE GMDN

The Global Medical Device Nomenclature (GMDN) is the world's foremost standard for naming, defining, and categorising medical devices.

Established in 1991, the first international workshop on medical device nomenclatures was held to create the GMDN. Initially started by the European Standards Organisations (CEN) and later supported by the Global Harmonisation Task Force (now the International Medical Device Regulators Forum – IMDRF) to help accelerate the harmonisation of medical device regulation globally. The GMDN is recommended by the IMDRF and is now used by circa 70 national medical device regulators across the globe.

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.

INTRODUCING GMDN

GMDN's Commitment to Independence & Global Service

- The GMDN Agency is structured as a non-profit, independent charity, governed by a Board of Trustees representing the medical device sector from around the world. This ensures that the GMDN Agency does not prioritise any single jurisdiction or region but instead provides equal access and service to all stakeholders globally.
- Independence is maintained through regular scrutiny by advisory groups such as the Technical Advisory Group (TAG) and the Authorities Strategic Advisory Group (ASAG), which include representatives from multiple countries and regulatory bodies. This governance model prevents regional bias and supports the needs of a diverse, International user base.
- Timely and responsive membership services, GMDN Term support, bespoke training sessions, and more, which are unique to GMDN compared to other nomenclatures.

GMDN CASE STUDY: WHO COLLABORATION

In July 2024, the WHO launched its open-access medical devices information system (MeDevIS) to support countries in identifying the appropriate medical devices for their healthcare systems.

The GMDN Agency collaborated with the WHO to map device descriptions within MeDevIS to GMDN, ensuring harmonisation and consistency in device identification. In parallel, the Agency mapped the WHO's Essentials Diagnostics List (EDL) to GMDN, supporting efforts to guide the development of national essential diagnostics lists (NEDLs).

These mappings provide clear, concise generic device descriptions that enhance interoperability across Databases and stakeholders. As GMDN is a dynamic dataset, the Agency remains committed to maintaining both mappings through ongoing review.

INTRODUCING GMDN

Transparency & Accountability

Regular reviews, stakeholder consultations, advisory group consultations and annual surveys ensure that GMDN continues to meet international requirements and supports the evolving landscape of medical device regulation. The Agency's commitment to transparency and technical excellence has made GMDN the trusted choice for regulators, healthcare providers, and manufacturers worldwide.

"From my point of view the GMDN nomenclature is the most widely represented worldwide. It is easy to understand and use. There are notifications about new Codes and changes from the GMDN Agency. There is good support available."

Manufacturer (Germany)

Supporting Harmonisation Through Collaboration

GMDN collaborates with global stakeholders, including WHO, UNICEF, SNOMED and JIC.

These partnerships help align nomenclature standards across jurisdictions, facilitating harmonisation while allowing GMDN to maintain its own governance and standards.

"Based on my limited experience, I prefer the GMDN Agency search engine to identify appropriate Codes than the CND list (EMDN). The GMDN Codes have clear definition presented in a more detailed manner."

Manufacturer (USA)

"Very convenient to research and the definition is clear."

Manufacturer (China)

INTRODUCING GMDN

"I think GMDN is the ideal platform."

Manufacturer (Colombia)

"Provides more detailed descriptions and is easier to search (more intuitive) than the current EMDN Database (although the EMDN might get better)."

Manufacturer (France)

Strengths of GMDN Compared to Other Nomenclature Systems

Global Reach and Inclusivity: GMDN is trusted in over 140 countries and is designed to serve regulators, manufacturers, and healthcare providers worldwide, not limited to the priorities of any single region.

Multi-Hierarchical Classification: Unlike single-hierarchical systems (such as EMDN or UNSPSC), GMDN's multi-hierarchical approach allows for mutually-exclusive Terms and clinically relevant definitions, supporting more precise device identification and categorisation.

Real-Time Updates: GMDN is updated continuously, ensuring that new technologies and regulatory requirements are reflected promptly. Other systems may only update annually or bi-weekly, which can delay the adoption of innovations.

Clinically Relevant Definitions: GMDN Terms include definitions with intended use and important clinical attributes, supporting regulatory submissions, surveillance, and safety signal detection. Some other nomenclatures lack clinically relevant definitions or are less granular.

Flexible Access Models: GMDN offers both free of charge and paid options, funded by registered members, making it accessible to a wide range of stakeholders.

"I find GMDN easy to work with and providing an extended variety of devices (always growing) with a good description of their application."

Consultancy (Netherlands)

"Because the Codes provide a standardised language for medical devices that helps regulators and manufacturers track devices, monitor safety trends, and facilitate international market access."

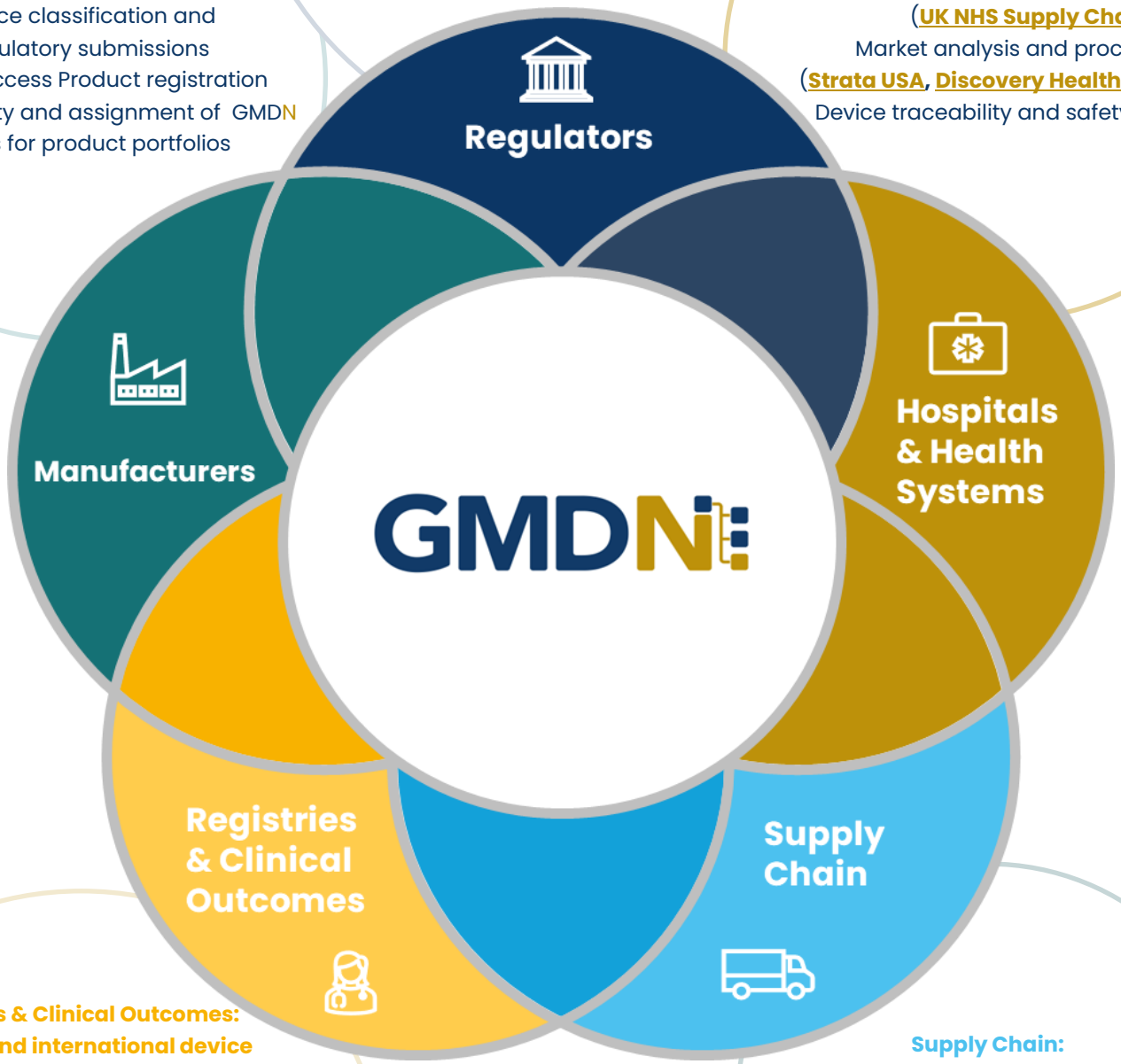
Manufacturer (South Africa)

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

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

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



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

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

GMDN UTILITIES

The GMDN Database's primary utility is to provide a globally harmonised, standardised system for naming and categorising all medical devices. It serves as a common language for various stakeholders in the healthcare industry to communicate and share information consistently across different countries and regions. Key utilities of the GMDN Database include:

Regulatory Compliance: Regulatory authorities in approximately 70 countries (including the U.S. FDA, MHRA in the UK, and TGA in Australia, excluding EU.) require manufacturers to use GMDN Codes in their device registration and submissions. The GMDN Code is a key data element in global Unique Device Identification (UDI) systems, which helps trace devices throughout their lifecycle.

UDI:, A system of unique numeric/alphanumeric Codes for medical devices, enabling tracking from manufacturing to use, has components of a Device Identifier (DI) and a Production Identifier (PI) for batch/serial info, captured in barcodes. UDI systems need a robust, up-to-date, globally accepted nomenclature to fulfil their purpose of enhancing patient safety, improving supply chain management, and enabling better recall/monitoring/signal detection of devices.

There are multiple challenges in UDI implementation, including multiple UDI-DIs for the same model of device, different UDI triggers in different jurisdictions, the impact of multiple standards for UDIs (one per issuing agency) on cost and time to implement in healthcare, different positions on the UDI carrier, differing Codes/values for data fields in the UDI Databases, and various exceptions in different jurisdictions.

GMDN, as part of the UDI systems standardises device definitions and categorisation/ grouping beyond the single-device information, enabling faster and more reliable analysis and signal detection.

GMDN UTILITIES

Patient Safety & Vigilance: By using a single, clear nomenclature, the GMDN facilitates the identification and reporting of adverse events or problems associated with specific types of medical devices. This enables more effective post-market surveillance, faster and more targeted product recalls, and helps in the early detection of performance issues.

Effective Communication & Data Exchange/Interoperability: Provides a single, standardised language for identifying medical devices across the healthcare and medical technology landscape. Each GMDN Term consist of a unique generic name, definition and a 5-digit numerical Code, which allow different stakeholders to exchange information without the ambiguity associated with local language differences, naming conventions or manufacturer proprietary names. This ensures devices are recognised and described consistently across geographical borders and regulatory jurisdictions. It is aligned with international regulatory frameworks to support interoperability, enabling consistent data reporting across regions for both pre-market and post-market activities. Our enquiry process ensures the nomenclature keeps pace with innovation, so new and evolving technologies are captured, coded and exchanged. These features enable the GMDN to function as a common language, enabling reliable data sharing comparison and analysis, across an otherwise fragmented ecosystem.

Procurement & Inventory Management: Healthcare providers, such as hospitals and national health systems like the NHS in the UK, MTPReg group owned by the Swedish public healthcare providers, and the public hospitals use the GMDN for inventory control, purchasing processes, cost analysis, and managing medical equipment registers. This ensures consistent grouping and management of products.

Data Analysis & Healthcare Intelligence: The standardised data from the GMDN allows for robust analysis of device performance, cost variations, and care delivery, which can improve financial, operational, and quality outcomes. Researchers can aggregate data from similar devices made by different manufacturers, providing a comprehensive understanding for clinical decisions.

Global Harmonisation: Managed by the non-profit GMDN Agency, the system supports global efforts towards harmonising medical device regulations, reducing the burden on manufacturers who sell internationally. This is supported by collaborations with organisations like the World Health Organisation (WHO), the International Medical Device Regulators Forum (IMDRF) and Global Harmonization Working Party (GHWP).

The GMDN Database is dynamic, continually updated by expert developers to accommodate new technologies and changes in the MedTech landscape, ensuring its ongoing relevance and effectiveness. Access to the GMDN Database is available through the GMDN Agency website.

GMDN STRATEGIC FOCUS: 2026 — 2030

Support Global Harmonisation

By providing GMDN – a unified, up-to-date, standardised, global medical device nomenclature

Collaborate with international regulatory bodies and standards organisations to align Terminology frameworks.

Regularly update and refine definitions to reflect technological advancements and emerging device Categories.

Continue to develop new functionalities and user-friendly services to lower barriers to GMDN adoption.

Where we expect to be by 2030

GMDN aims to remain the leading medical device nomenclature, most widely adopted globally. The importance of a unified global nomenclature for enhancing patient safety will be acknowledged by key stakeholders worldwide.

GMDN CASE STUDY: STRATA DECISION TECHNOLOGY

At Strata, we empower healthcare organisations with software and data solutions to develop achievable budgets, effective strategic plans, and leverage data for market opportunities and growth. Our partnership with the Global Medical Device Nomenclature (GMDN) Agency helps these organisations categorise and analyse complex medical device data, enhancing patient care through efficient data management.

Healthcare leaders strive to improve financial, operational, and quality outcomes, often requiring deep data analysis. To facilitate this, we've launched a project to provide a logical grouping structure for high-cost areas of the hospital charge master. By using the GMDN Database, we ensure detailed and consistent data analysis, enabling faster and more accurate insights into cost variations and care delivery.

GMDN STRATEGIC FOCUS: 2026 — 2030

Integrate GMDN Data into regulatory Databases, supply chain management, inventory management systems and clinical systems.

Provide Term assignment support and technical guidance for system integration, ensuring seamless data exchange.

Promote adoption through training, outreach, and demonstration of interoperability benefits.

Facilitate Interoperability
Across health data systems, supporting regulators, manufacturers, and healthcare providers worldwide

Where we expect to be by 2030

The GMDN Database and its services will be modernised and advanced, with APIs and AI-powered tools improving search functionality, GMDN Term assignment, stakeholder services and real-time health systems integration.

GMDN CASE STUDY: GMDN IN A SWEDISH CONTEXT

The Global Medical Device Nomenclature (GMDN) was introduced in Sweden in 2011, coinciding with the formation of the MTPReg group.

This group is responsible for setting Codes for all medical equipment owned by Swedish public healthcare providers. Sweden's decentralised healthcare system, managed by regions, local authorities, or municipalities, is divided into public and private sectors. Each of the 21 regions has its own medical equipment register, with Codes set by the MTPReg group.

The MTPReg register synchronizes nightly with all regional registers to ensure new Codes are available locally.

GMDN STRATEGIC FOCUS: 2026 — 2030

Address emerging challenges
Including political divergence in regulatory approaches by fostering international collaboration and adaptive governance

Establish forums and working groups to identify and address adoption gaps, facilitate dialogue among diverse stakeholders and jurisdictions.

Monitor and respond to regulatory changes, evolving new standards, adapting nomenclature and governance structures as needed.

Invest in research and partnerships to understand and manage the impact of AI on the medical device ecosystem and regulatory processes.

Where we expect to be by 2030

The GMDN will remain as a trusted partner in the global medical device ecosystem by its commitment to international collaboration overcoming divergence and division with offering a unified, global and sustainable nomenclature.

GMDN CASE STUDY: INNOVATION OBSERVATORY

The NIHR Innovation Observatory, hosted by Newcastle University, project is working to identify and categorise premarket innovations using online sources e.g., patents, research papers, news articles.

After reviewing existing nomenclatures/classifications the GMDN was chosen as the most appropriate for their needs. A categorisation engine has been developed whereby the innovative products are assigned to the most appropriate GMDN Term so that higher level groupings to GMDN Categories are derived.

The GMDN Agency is working closely with the project to assist with making the tool as efficient as possible and there is considerable interest from the health service (e.g. NHS, NICE) in using the tool for horizon scanning and service planning/provision.

OUR VISION

To unify the global medical device community through a common nomenclature, underpinned by robust terminology, taxonomy and supporting data infrastructure and services – driving harmonisation, reducing regulatory burden, and enabling equitable access to safe and effective technologies.

OUR MISSION

We deliver a globally harmonised medical device nomenclature that safeguards public health by enabling seamless data interoperability, traceability, and informed decision-making across regulatory and healthcare systems.

OUR VALUES

Leadership

Setting the global standard for medical device nomenclature and supporting global harmonisation.

Collaboration

Working closely with stakeholders across the healthcare ecosystem.

Innovation

Responding to evolving stakeholder needs with agility and creativity.

Integrity

Operating with honesty and transparency.

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