How GMDN meets the WHO requirements for a global nomenclature for medical devices

The World Health Organisation has published its requirements for a medical device nomenclature to meet their needs (WHO EB148/13). Here is the list of their requirements and how we are currently meeting them.

WHO requirement	**How the GMDN Agency meets or exceeds the requirement**
Q1. Governance. Are organisational and review structures in place to ensure that all stakeholders from different regions can provide feedback according to global needs?	The GMDN Agency is a charity regulated by the UK Government, and its Board of Trustees are all volunteers. The Board has several advisory committees that provide the users of the GMDN and its many stakeholders with representation: • The 'Authorities Strategic Advisory Group' represents the specific interest of medical device regulators and is open to all qualified organisations. • The 'Policy Advisory Group' represents the interests of all stakeholders on operational issues related to the management of the GMDN. Membership of the PAG is by application by any representative organisation. • The 'Appeals Committee' is responsible for considering any matters relating to complaints about the drafting of GMDN Terms. The committee is independent of the Term Development team of the Agency. Membership of the GMDN Agency is free to any organisation. Any registered member interested in viewing GMDN Codes can do so for free. Members can also request and review any new work without any charge.

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Q2. What are the classification, coding and nomenclature characteristics? Do they include a transparent methodology?	Updating of the GMDN is monitored and controlled by a ISO9001 Quality Management System. Our QMS is certified by a third-party auditor. More information about how we update the GMDN can be found here. Any Member can view the new GMDN Terms that are being proposed and can provide a comment on the new Term or ask a question. In the case of dispute, the Member can request and independent review of our work.
Q3. Is there a process and a transparent mechanism for regular updates?	Any Member can submit a request to update the GMDN. The GMDN is updated daily to meet the needs of medical device regulators for urgent changes, such as in response to a global pandemic. Each month regular updates of the GMDN are made freely available to 100's of regulators, inter-government organisations, charities, researchers, and hospitals. Manufacturers of medical devices can also subscribe to a notification service concerning changes to GMDN Terms of interest to them. There is a charge for this service. Any Member can check on the status of any GMDN Term free of charge by using the GMDN website.
Q4. Are hierarchies grouped into categories and subcategories to meet stakeholder needs?	The GMDN has multiple hierarchies of categories to meet the different priorities for medical device regulators and other users. Multiple hierarchies are preferred by users because it allows for better organisation and searching.

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Q5. Is the nomenclature available for medical devices used outside highly regulated countries?	The GMDN has been provided to users in more than 180 countries. The GMDN is widely used by medical device regulators and other government authorities in more than 100 countries. The GMDN includes descriptions for products that are widely recognised as medical devices and related products such as hospital laboratory equipment and complimentary therapeutic devices. Because the GMDN has been used globally for many years it must include all devices, including those that are no longer in wide commercial distribution.
Q6. Are there mutually exclusive terms?	The GMDN includes only mutually exclusive Terms. The GMDN in addition has Definitions that accurately describe each GMDN Term to aid selection.
Q7. Is there availability of terms in other languages?	The GMDN is published in English. The GMDN been translated into four more UN official languages, plus several other languages. Other translation languages will be considered on request.
Q8. Access to information. Information should be capable of being referenced and used by regulators, procurers, managers, and all users of medical devices (hospitals/health care workers and patients)	All regulators and hospitals can obtain GMDN data files to meet all their needs. This includes referencing in public documents to support any purpose. The GMDN is currently widely used by regulators and hospitals to support patient care.

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Q9. Is the nomenclature freely available?	The GMDN is available to all, free of any charge. The GMDN is widely recognised by regulators, hospitals, and academics as the nomenclature to aid the accurate identification of medical devices and thereby support patient care. In the interest of data protection, we ask that users register at the GMDN website as Members, so we can best identify and meet their needs.
Q10. Does the nomenclature support unique device identifier system?	The GMDN was chosen for the first national UDI Database (US FDA GUDID) in 2015. Since that time most other national UDI Databases have made the use of the GMDN a requirement.
Q11. Is the nomenclature accessible through simple and intuitive search?	The GMDN browser has a simple search tool and a hierarchical search function that groups GMDN Terms by hierarchy or attribute.
Q12. Is the nomenclature available for use in all health-related data base systems?	The GMDN is used in many health-related database systems today to support the management of medical equipment and inventory completely free of any charge. If you have any questions related to the access and use of GMDN in your organisation, please contact us for more information.