GMDN alignment with the requirements for medical devices mentioned in WHO EB152/11 document (https://apps.who.int/gb/ebwha/pdf_files/EB152/B152_11-en.pdf)

The World Health Organisation Secretariat proposed principles of an international classification, coding and nomenclature of medical devices. The latest version of the principles is stated in WHO document EB152/11.

Under the principles, the international classification, coding and nomenclature of medical devices would need:

(a) to ensure that all stakeholders from different regions can provide feedback;
(b) to provide classification, coding and nomenclature characteristics with a transparent methodology and processes for updates; and
(c) to provide a source where information will:
    (i) be capable of being referenced and used by regulators, procurers, managers and all users;
    (ii) be freely available and considered a global public good;
    (iii) support the Unique Device Identification system;
    (iv) be accessible through a simple and intuitive search; and
    (v) be available for use in all health-related database systems.

Although it is the GMDN Agency's contention that these principles have not been adopted widely by medical device regulators, the GMDN Agency would like to set out its interpretation of these principles, along with details as to why the GMDN Agency considers it meets these requirements.

WHO principle	Why the GMDN Agency considers it is aligned with the principle
to ensure that all stakeholders from different regions can provide feedback;	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 as detailed below: • The 'Authorities Strategic Advisory Group' represents the specific interest of medical device regulators and is open to all regulatory authorities that use the GMDN. • The 'Policy Advisory Group' represents the interests of all stakeholders on operational issues related to the management of the GMDN. Participation of the PAG is taken from the widest range of stakeholders and is free of any cost. • The 'Appeals Committee' is responsible for considering any matters relating to complaints from any person/entity about the drafting of GMDN Terms that cannot be resolved using our normal Term Enquiry process. The committee is independent of the Term Development team of the Agency. Access to GMDN is free to any organisation in any country which will allow you to: • Access all Term Names, Definitions and Codes • View proposed new or changes to Terms • Provide comments or ask questions and submit Enquiries. Registration to GMDN supports data integrity, timely updates, and opportunities to contribute to the global resource.

WHO principle	Why the GMDN Agency considers it is aligned with the principle
to provide classification, coding and nomenclature characteristics with a transparent methodology and processes for updates;	Updating of the GMDN is monitored and controlled by an ISO9001 Quality Management System. Our QMS is annually audited by a third-party Certification Body. More information about how we update the GMDN can be found here. Anyone can view the new GMDN Terms that are being proposed and can provide a comment on the new Term or ask a question before the changes are made. In the case of a dispute over the wording in the Term which cannot be resolved using our normal Term Enquiry process, the Member can request an independent review of our work by application to the Appeals Committee. Anyone can submit a request to update the GMDN. The GMDN is updated in real time with daily/monthly updates provided to the user as required. Updates are made to include changes required to meet the needs of stakeholders, and for urgent changes, special requests can be made by regulators, 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. Anyone can check on the status of any GMDN Term free of charge by using the GMDN website. Manufacturers of medical devices can in addition, subscribe to an automated notification service concerning changes to GMDN Terms of interest to them. There is a charge for this service.

WHO principle	Why the GMDN Agency considers it is aligned with the principle
to provide a source where information will: be capable of being referenced and used by regulators, procurers, managers and all users	Anyone who registers to view GMDN Codes can do so for free. Anyone can also request and review any new work without any charge. Registration uses a simple web form completed on our website. The GMDN is published in English. The GMDN has been translated into four of the UN's official languages (Spanish, French, Russian and Chinese), plus several other languages. There is no cost for anyone to access any of the language translations of the GMDN. Other translation languages will be considered on request. The GMDN has been provided to our 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. We are constantly revisiting the list of products to make it as comprehensive and useful to stakeholders as possible. Because the GMDN has been used globally for many years, it must include all devices, including legacy products which are still likely to be in use, but which are no longer being commercially distributed widely to any significant degree.

WHO principle	Why the GMDN Agency considers it is aligned with the principle
to provide a source where information will: be freely available and considered a global public good	The GMDN is available to all, free of any charge (subject to any charges payable in relation to subscriptions to notification services regarding changes to the GMDN). 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. We require all users to register at the GMDN website to preserve the integrity and security of the database, so we can communicate directly with them and meet our regulatory requirements for data protection. This is the same requirement to register on the WHO website to see the WHO-FIC (ICD-11 draft items). All the users of the GMDN must respect the copyright and registered trademark of the GMDN Agency, which we note the WHO also requests of its users.
to provide a source where information will: support the Unique Device Identification 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, and the GMDN data is able to be shared with national stakeholders to meet their needs. No other nomenclature is currently being used in a national Unique Device Identifier System, which is in a fully tested production status. (EUDAMED is still in the test phase of implementation)

WHO principle	Why the GMDN Agency considers it is aligned with the principle
to provide a source where information will: be accessible through a 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. The GMDN has multiple hierarchies of categories to meet the different priorities of medical device regulators and other users. Research shows that multiple hierarchies are preferred by users because it allows for better organisation and searching. The GMDN includes only mutually exclusive Terms. The GMDN, in addition, has meaningful Definitions that accurately describe each GMDN Term to aid selection.
to provide a source where information will: be available for use in all health-related database systems.	The GMDN is available to all health-related database systems and is already used in many health-related database systems today to support the management of medical equipment and inventory completely free of any charge to support patient care. As has been detailed above, all regulators and hospitals can register to use the GMDN free of charge and access GMDN data files to meet all their information needs to help identify and group medical devices. This includes referencing relevant GMDN Codes, Terms and Definitions where required in public documents to support any purpose. If you have any questions related to the access and use of GMDN in your organisation, please contact us for more information.