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Dear Medical Device Regulator,

The Global Medical Device Nomenclature (GMDN)

The GMDN is a system of internationally agreed generic descriptors used to identify all medical device products. Such products include those used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans.

The main purpose of the GMDN is to provide health authorities and regulators, health care providers, medical device manufactures and suppliers, conformity assessment bodies and others with a single generic naming system that will support patient safety. The GMDN is based on the international standard ISO 15225.

The GMDN meets the need to identify medical devices at the global level, as identified by the Global Harmonization Task Force (GHTF) and is being implemented by regulators in many countries as part of their national medical device vigilance systems.

GMDN is managed by the GMDN Agency, a non-profit organization, which reports to its Board of Trustees, that represents medical device regulators and industry. The GMDN Agency releases updated GMDN terms on a daily basis, on their interactive website.

As a Medical Device Regulator, we invite you to access the GMDN database for national implementation. There is no cost for access to the GMDN for regulators. Regulators can use the GMDN to support the register of medial devices and the exchange of information between regulators.

We would recommend that you nominate a member of your staff to be our contact person and coordinate training with your organisation. This person should manage access to the GMDN database and security of the codes within your organisation. We suggest they register for access at our website www.gmdnagency.org and we will be able to provide them support and training.

Please let me know if you need any further information about the GMDN and its use by Regulators at any time.

Yours sincerely

Mark Wasmuth

CEO

GMDN Agency