



MARCH 2011

Why choose the Global Medical Device Nomenclature GMDN?

Technical Merit **Excellent**

Number of terms (Jan 2011):

Number of collective terms: For all MDs: 1961 / in particular for IVDs: 319

Number of preferred terms: For all MDs: 19952 / in particular for IVDs: 10580

Easy and global access via the web to the continuously updated data base

Future Development **Excellent**

Objectives for developments of new terms by 2011:

Number of collective terms: For all MDs: 380 / in particular for IVDs: 10

Number of preferred terms: For all MDs: 2500 / in particular for IVDs: 2000

Languages

Terms available in **English today**

- Soon available in **25 European languages** (in course of translation by EU Commission) and in **Chinese and Turkish**

Popularity **Recognised at International level**

Based on a **CEN/ISO** standard: EN/ISO 15225 "Medical Devices – Quality Management – Medical Device Nomenclature data structure (Second edition 2010-058-01)

Supported by Regulatory Affairs Authorities, in particular by the **European Commission, FDA** (US), **TGA** (Australia), which are involved in the development of the nomenclature and in its governance

Supported by **WHO**, involved in the governance of GMDN - Supported by the Global Harmonisation Task Force (**GHTF**) and the Asia Harmonisation Working party (**AHWP**), involved in the governance of GMDN

Supported by Industry associations worldwide: AdvaMed (US), COCIR, EDMA, Eucomed, EuromV1, (Europe), MEDEC (Canada), MTAA (Australia), JFMDA (Japan) involved in the governance of GMDN

Governance **Excellent**

Not-for-profit Agency. Broadly-based international and representative Board of Trustees and Policy Advisory Group

Board of Trustees (7)

- 2 nominees of GHTF governments
- 1 industry nominee
- 2 previous trustees
- 2 member of AHWP

Policy Advisory Group

- 5 representatives of GHTF founding governments (US, Canada, Japan, Australia, Europe)
- 5 representatives of AHWP founding governments
- 5 industry representatives
- 1 representative of WHO

GMDN maintenance Agency



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Long-term Commitment

Excellent

GHTF, AHWP, the European Commission, FDA, TGA are actively participating in the Governance processes, and have provided and continue to provide technical expertise and public support.

Charges

**Free of charge for Regulators
Minimal for manufacturers**

GMDN Maintenance Agency is a non-for-profit company. The current license fee based funding system is under revision. A new business and licensing model is under development, with a view to it being implemented within 12 months and no later than 2 years, **but the access to GMDN is already free for all regulators who support the use of GMDN.**

Sustainability

Good

The GMDN Maintenance Agency was created according to a resolution of the CEN Technical Board (BT), following a request from CEN/TC 257/SC1 "Nomenclature for medical devices" for a Maintenance Agency on GMDN. By resolution of CEN BT "2000 – RESOLUTION BT 17/2000 (47BT: item 3.5)" the responsibility for the maintenance of GMDN was given to a selected Maintenance Agency through BSI who accepted that this responsibility is passed to the appropriate body formulated and now legally constituted as GMDN Agency (a non-for-profit company established under UK law). The GMDN Agency is based on the Articles of Association of the GMDN Agency and the Memorandum of Association of 10 February 2005.

Impact on trade

Good

Development of many national nomenclature/classification initiatives have hitherto resulted in proliferation of costs relating to product identification / registration all paid for by the manufacturers.
The adoption of GMDN as the recognised global nomenclature therefore results in considerable cost savings and simplification of product registration procedures

Impact on governments

Regulatory

Intended to be used for **Registration** of Medical Devices by regulatory bodies worldwide including GHTF and AHWP members, 21 European countries, American countries, Australia, Turkey etc.

- To be used in the exchange of data between regulatory bodies to in particular facilitate **Market surveillance** and follow-up of adverse incidents, for example in Europe (in the European databank EUDAMED).
- To be used for Identification of Medical Devices in the **Unique Device Identifier (UDI)** database - See GHTF UDI guidance