Questionnaire regarding nomenclatures for concepts related to health technologies

1. Name of the "nomenclature"

   Global Medical Device Nomenclature (GMDN)

2. Name and legal status (Inc, Plc, Ltd, …) of the organization that manages the nomenclature system

   GMDN Agency Ltd

3. The organization that manages the nomenclature

   a. Please describe the governance and management of the body responsible for maintaining the nomenclature.

      The GMDN Board of Trustees oversees the management and strategy of the GMDN Agency. See attached Governance Document (BOT 04) for full details. A Register of Trustees is attached (BOT 19).

   b. How is broad stakeholder representation ensured?

      The GMDN Policy Advisory Group represents Stakeholder interests in the development and access to the GMDN. A list of PAG Members are attached.

   c. How is broad geographical representation ensured in governing bodies?

      The PAG representation is taken from the original 5 Regulators from GHTF countries, 5 Regulators from the AHWP, 5 representatives from Industry and one representative from the WHO. Other Members will be considered as the use of the GMDN grows in other regions of the world, ie Africa, South America, etc.

4. Background to the creation of the nomenclature

   Please outline the scope of the mandate to engage in classification and naming

   The mandate for the development for the GMDN is from ISO15225, following a recommendation from the GHTF.

5. What is the intended purpose/use of the system?
The GMDN is intended for the following purposes:

To give a common generic descriptor for medical devices having similar features, characteristics and intended use.
To be used in the exchange of data between regulatory bodies to in particular facilitate market surveillance and follow-up of adverse incidents.
To be used for the exchange of data in the healthcare community.

6. Mandatory use of the nomenclature
   a. Has any country or organization made it mandatory to use the nomenclature for specific purposes?

A number of countries have mandated the use of the GMDN for product registration purposes. The list of countries mandating the use of GMDN is expanding and some countries / regions, such as the EEA, are implementing new regulations this year to require manufacturers to use the GMDN for product registration. The list to date is:
Australia
Japan
Italy
Greece
Poland
Czech Republic
Estonia
Portugal
Turkey
Croatia
Peru
Mozambique

7. Please comprehensively describe the structure of the system. The structure and format of terms, the relations between terms, design principles for creating terms etc. Current IT implementations by the "management organization" and by users are also of interest.

The GMDN is a polyhierarchical system.
Preferred Terms are flat and linked to Collective Terms (device attributes and high-level terms) which are used to create polyhierarchies.
Collective Terms allow searches by subject group. CTs allow analysis of the GMDN by product attribute or feature
More comprehensive information can be found in the attached GMDN User Guide.

8. Are the terms used in the classification system generic i.e. non proprietary?
All the terms uses for classification (GMDN Preferred Terms) are generic and non-proprietary. For historical reasons, proprietary names have been included as ‘Synonyms’ within the database which navigate to Preferred Terms.

9. **Maintenance of the nomenclature system**
   a. **How is the system maintained?**

   The GMDN is maintained daily by a team of medical device nomenclature experts, following manufacturer requests for new terms.

   b. **Please describe the process for creating or modifying terms in the system.**

   Application for new terms is made by GMDN Registered Members using an on-line application process. This process tracks communication between the manufacturers and GDMN expert team.

   c. **How is transparency ensured with regard to development and maintenance of the nomenclature?**

   The development of new terms is a partnership between the manufacturers (product expert) and GMDN nomenclature expert. The authorisation for a new term is by a second GMDN supervising expert. Complaints by manufacturers regarding new terms is managed via an independent Appeals Committee.

10. **Different language versions of the nomenclature**
    a. **How is the translation of terms and definitions managed?**

    The Translation of the GMDN Database is managed by Regulators who wish to undertake registration as a GMDN Translator. The GMDN Database provides facilities to upload translations and allow access to all registered members.

    b. **What language versions exist as of February 2011?**

    Translations are managed via a dedicated Translators License.

    c. **What language versions are under translation as of February 2011?**
11. Endorsement of the nomenclature system

a. Has the system been endorsed by stakeholders (healthcare professionals, Ministries of Health, industry, regulatory bodies etc.)?

[ ] Yes  [ ] No

Please indicate the names of the entities which have endorsed the system.

GHTF have endorsed the GMDN. The GMDN is being implemented by the European Commission for use by EU Member States for its EUDAMED system. The US FDA has selected the GMDN as the nomenclature for its proposed UDI registration system.

The Australian TGA has used GMDN for product registration for over 5 years. The Japanese MHLW has used the GMDN as the bases for product registration for several years.

Other governments are implementing the GMDN to meet local needs.
12. Implementation in IT systems, interoperability and intellectual property

a. Please outline the intellectual property state of the nomenclature system. Please include reference to the ownership of the terms used.

The GMDN database is maintained by the GMDN Agency on behalf of its stakeholders. The GMDN database is an on-line system. Access to the database is only available registered members.

b. Is the system available as a package for integration into user IT systems (maintenance management, adverse event reporting, procurement…) ? ☑ Yes  ☐ No

c. Please specify the conditions of agreements for use in user IT systems.

The GMDN database is available as an XML format file to download into an IT system. This is only necessary for Regulators and Healthcare Providers. The data should be kept secure from public access. There is no charge for this service.

13. Interoperability

Please specify compatibilities ensured and mappings to other nomenclatures maintained.

The GMDN has been developed from several original nomenclatures, namely:
ECRI – UMDNS nomenclature
EDMA nomenclature
FDA - CDRH nomenclature
ISO 9999 nomenclature
Japanese – MHLW/JFMDA nomenclature
Norwegian – NKKN nomenclature,

Close co-operation between these organisations and the GMDN Agency are maintained, except with ECRI who withdrew from cooperation several years ago for an unspecified reason.

14. Model for sustainable financing
a. **How is the system financed? I.e. user fees, member fees, subscriptions, one off payments, open source?**

The GMDN Agency is a non-profit distributing organisation, not linked to any private organisation to promote their goods or services. A balanced budget for the GMDN Agency is set each year by their Board of Trustees and profits are reinvested to improve access to the GMDN Codes.

b. **What is the cost of the nomenclature to specific users (governments, industry, health care providers)?**

The cost to Regulators (Governments) is free. Industry pays according to their size according to a formula. The minimum cost is 100 EUR per year for the smallest company size. Healthcare Providers pay 600 EUR per year. GMDN Members are not restricted to use the GMDN within any proprietary software.