Questionnaire regarding nomenclatures for concepts related to health technologies

1. **Name of the "nomenclature"**

ISO 9999 Assistive products for persons with disability. Classification and terminology

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

International Organization for Standardization (www.iso.org)
ISO is a Non-Governmental Organization (NGO)

3. **The organization that manages the nomenclature**

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

   The work of preparing International Standards is normally carried out through ISO subcommittees and working groups operating under the direction of ISO technical committees. Technical Committee ISO/TC 173, Assistive products for persons with disability is responsible for ISO 9999

   b. **How is broad stakeholder representation ensured?**

   Stakeholders in international standardization comprise all those groups who have an interest in international standardization because they are affected by it and wish therefore to contribute to the process of the development of International Standards. Stakeholders participate in the technical work of ISO through national delegations appointed by the member bodies of ISO or, if they are organized in international or broadly-based organizations, through liaison organizations.

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

   ISO is a worldwide federation of national standards bodies (ISO member bodies). Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-govermental, in liasion with ISO, also take part in the work.

4. **Background to the creation of the nomenclature**

Please outline the scope of the mandate to engage in classification and naming
5. **What is the intended purpose/use of the system?**

ISO 9999:2007 establishes a classification of assistive products especially produced, or generally available, for persons with disability. Assistive products used by a person with disability, but which require the assistance of another person for their operation, are included in the classification.

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

Yes for example: In national assistive technology databases (e.g. Denmark, Israel, USA); hospitals use it in their assistive technology logistic (e.g. Portugal, Finland, Norway); research reports, epidemiology and national statistical studies (Australia)

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.**

Assistive products are classified according to their function. The classification consists of three hierarchical levels termed classes, subclasses and divisions. Each class, subclass and division consists of a code, a title and, if necessary, an explanatory note and reference to other parts of the classification. Explanatory notes are used to clarify the content of the class, subclass or division. Inclusions and exclusions are used to provide examples.

8. **Are the terms used in the classification system generic i.e. non proprietary?**

Yes they are.

9. **Maintenance of the nomenclature system**
   a. **How is the system maintained?**
International Standards are developed by ISO technical committees (TC) and subcommittees (SC) by a six-step process:
Stage 1: Proposal stage
Stage 2: Preparatory stage
Stage 3: Committee stage
Stage 4: Enquiry stage
Stage 5: Approval stage
Stage 6: Publication stage

Most standards require periodic revision. Several factors combine to render a standard out of date: technological evolution, new methods and materials, new quality and safety requirements. To take account of these factors, ISO has established the general rule that all ISO standards should be reviewed at intervals of not more than five years. On occasion, it is necessary to revise a standard earlier.

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

There are three main phases in the ISO standards development process as follows. The need for a standard is usually expressed by an industry sector, which communicates this need to a national member body. The latter proposes the new work item to ISO as a whole. Once the need for an International Standard has been recognized and formally agreed, the first phase involves definition of the technical scope of the future standard. This phase is usually carried out in working groups which comprise technical experts from countries interested in the subject matter. Once agreement has been reached on which technical aspects are to be covered in the standard, a second phase is entered during which countries negotiate the detailed specifications within the standard. This is the consensus-building phase. The final phase comprises the formal approval of the resulting draft International Standard (the acceptance criteria stipulate approval by two-thirds of the ISO members that have participated actively in the standards development process, and approval by 75% of all members that vote), following which the agreed text is published as an ISO International Standard.

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

The process of standardization is an open process. Stakeholders can participate through the National Standardization Organizations. Participation can be active, i.e. contributing in the development and maintenance of the standards, or passive, i.e. voting on working drafts, insight in documents, possibility of giving input through comments, etc.

10. **Different language versions of the nomenclature**
11. Endorsement of the nomenclature system

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

   X Yes    [ ] No

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

National Institute for Health and Welfare in Finland has adopted it to be used in the electronic health records system (www.kanta.fi/web/en/frontpage).
The INTERBOR Nomenclature (prosthesis and orthosis) used by INTERBOR members uses ISO 9999 as it backbone to specify the type of p & o devices available (http://interbor.org).
Korea has enacted a law related to long-term care insurance for elderly, they refer to ISO 9999 for selecting assistive products.
Denmark (www.hmi-basen.dk) Sweden (www.hinfo.se) and Norway (www.hjelpemiddeldatabasen.no) have AT database on Internet where all products are sorted according to ISO 9999.

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.

All rights of Standards are reserved, all ISO publications are protected by copyright. Intellectual property lies with ISO.
b. **Is the system available as a package for integration into user IT systems (maintenance management, adverse event reporting, procurement….)?**  
   □ Yes  
   x No

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


13. **Interoperability**

   Please specify compatibilities ensured and mappings to other nomenclatures maintained.

   There is work going on to integrate International Classification of Functioning, Disability and Health codes and ISO 9999 codes.  
   ISO 9999 codes are integrated to Global Medical Device Nomenclature GMDN

14. **Model for sustainable financing**

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

   Membership fees paid by National Member Bodies, contribution fees from participants with national standardization bodies, subscriptions, payment for Standards, no open source.

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

   CHF 192,00