Assistive Product Classifications and Regulations

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Classifications
ISO 9999 – Assistive products

Any product (including devices, equipment, instruments and software), especially produced or generally available, used by or for persons with disability

• for participation;

• to protect, support, train, measure or substitute for body functions/structures and activities; or

• to prevent impairments, activity limitations or participation restrictions.
ISO 9999 – Scope

**Includes** assistive products which are used by a person with disability, but which require the assistance of another person for their operation.

**Excludes** installation items, combinations of assistive products, medicines, implanted devices, products and instruments used exclusively by healthcare professionals, non-technical solutions and services, and financial support.
ISO 9999 – Structure

Assistive products (including software) are classified according to their function.

The classification consists of three hierarchical levels:

1. Class
2. Subclass
3. Division
ISO 9999 – Classes (from DIS)

12 classes, e.g., assistive products for:
• education and for training in skills
• self-care activities and participation in self-care
• activities and participation relating to personal mobility and transportation
• domestic activities and participation in domestic life
• communication and information management
• recreation and leisure
ISO 9999 – Subclasses (from DIS)

‘Assistive products for communication and information management’ includes, among others, assistive products for:

- seeing
- hearing
- voice production
- drawing and writing
- calculation
- face-to-face communication
- reading
ISO 9999 – Use

• Communication
• Prescription
• Supply
• Research
• Regulation
Purpose of regulations

To ensure that assistive products are safe and effective for their intended use.
International regulations

ISO 13485 ’Medical devices – Quality management systems’

Requirements for a quality management system for the design and manufacture of medical devices

WHO Wheelchair guidelines

Guidelines for the provision of wheelchairs in less-resourced settings
Regional regulations

European example:

Medical Devices Directive (MDD).

Requirements in relevant standards should be met.

Compliance with MDD gives access to the markets in all European countries.
Standards

General:
• EN 12182 ’Assistive products for persons with disability. General requirements and test methods’

Product specific (examples):
• ISO 7176 ’Wheelchairs’. More than 20 parts.
• ISO 16480 ’Wheelchair seating’. About 10 parts.
CE marking process

- User needs
- Regulatory requirements

- Product design
- Risk analysis
- Technical tests
- Clinical evaluation
- Documentation
- Product registration
- Affixing CE mark
- Marketing
- Surveillance & vigilance
Potential impact

If products comply with applicable regulations:
+ Manufacturers/suppliers can access more markets
+ Providers can provide safe and effective products
+ Users can be safe and perform better
- Payers need to pay more
- Products may be unsafe, ineffective or costly if variations in population (e.g., body size) and environment (e.g., brick vs. paved roads) are not taken into consideration
Potential impact

If products do NOT comply with applicable regulations:

+ Users are protected from harmful or ineffective products

- Users cannot access safe and effective products that do not formally comply with the requirements
Question

What trade-off between 

*users’ access to effective assistive products*

and

*product compliance with regulations or standards*

is acceptable – if any?