

DIN EN 12182:2012-07 (E)

Assistive products for persons with disability - General requirements and test methods

| Contents | Page |
|---|------|
| Foreword | 5 |
| 1 Scope | 7 |
| 2 Normative references | 7 |
| 3 Terms and definitions | 9 |
| 4 General requirements | 11 |
| 4.1 Risk analysis | 11 |
| 4.2 Intended performance and technical documentation | 11 |
| 4.3 Clinical evaluation and investigation | 12 |
| 4.4 Assistive products that can be dismantled | 12 |
| 4.5 Fasteners | 12 |
| 4.6 Mass limits | 12 |
| 4.7 Immobilising means | 12 |
| 4.8 Design requirements in relation to persons with cognitive impairment | 12 |
| 5 Materials | 13 |
| 5.1 General | 13 |
| 5.2 Flammability | 13 |
| 5.2.1 General | 13 |
| 5.2.2 Upholstered parts, mattresses, bed bases and bedding | 13 |
| 5.2.3 Upholstered parts | 13 |
| 5.2.4 Mattresses and bed bases | 13 |
| 5.2.5 Bedding | 14 |
| 5.2.6 Moulded parts | 14 |
| 5.3 Biocompatibility and toxicity | 14 |
| 5.4 Contaminants and residues | 14 |
| 5.4.1 General | 14 |
| 5.4.2 Substances which may leak from an assistive product in intended use and in fault conditions | 14 |
| 5.5 Infection and microbiological contamination | 15 |
| 5.5.1 Cleaning and disinfection | 15 |
| 5.5.2 Animal tissue | 15 |
| 5.6 Resistance to corrosion | 15 |
| 6 Emitted sound and vibration | 15 |
| 6.1 Noise and vibration | 15 |
| 6.2 Sound levels and frequencies of audible warning devices | 15 |
| 6.3 Feedback | 16 |
| 7 Electromagnetic compatibility | 16 |
| 7.1 General | 16 |
| 7.2 Emissions | 16 |
| 7.3 Immunity | 16 |
| 7.4 Power frequency magnetic field immunity | 16 |
| 8 Electrical safety | 17 |
| 8.1 General | 17 |
| 8.2 Electrical systems | 17 |

| | | |
|--------|---|----|
| 8.3 | Continuity of power supply | 17 |
| 8.4 | Battery powered assistive products | 18 |
| 8.4.1 | Battery housings | 18 |
| 8.4.2 | Connection | 18 |
| 8.4.3 | Charge level indicator | 18 |
| 8.5 | Circuit protection | 19 |
| 8.6 | Electronic programmable systems | 20 |
| 8.7 | Electrically heated blankets, pads and similar flexible heating appliances | 20 |
| 8.8 | Assistive products with skin contact electrodes | 20 |
| 8.9 | Ingress of liquids | 20 |
| 9 | Overflow, spillage, leakage, and ingress of liquids | 21 |
| 9.1 | Overflow | 21 |
| 9.1.1 | Requirements | 21 |
| 9.1.2 | Test method | 21 |
| 9.2 | Spillage | 21 |
| 9.2.1 | Requirements | 21 |
| 9.2.2 | Test method | 21 |
| 9.3 | Leakage | 21 |
| 9.4 | Ingress of liquids | 21 |
| 9.4.1 | Requirements | 21 |
| 9.4.2 | Test method | 22 |
| 10 | Surface temperature | 22 |
| 11 | Sterility | 22 |
| 11.1 | Sterility requirements | 22 |
| 11.2 | Sterilization processes | 22 |
| 11.3 | Maintenance of sterility in transit | 23 |
| 12 | Safety of moving parts | 23 |
| 12.1 | Squeezing | 23 |
| 12.2 | Mechanical wear | 23 |
| 12.3 | Emergency stopping functions | 24 |
| 13 | Prevention of traps for parts of the human body | 24 |
| 13.1 | Holes and clearances | 24 |
| 13.2 | V-shaped openings | 25 |
| 14 | Folding and adjusting mechanisms | 25 |
| 14.1 | General | 25 |
| 14.2 | Locking mechanisms | 25 |
| 14.3 | Guards | 25 |
| 15 | Carrying handles | 25 |
| 15.1 | General | 25 |
| 15.2 | Requirement | 26 |
| 15.3 | Test method | 26 |
| 16 | Assistive products which support or suspend users | 26 |
| 16.1 | General | 26 |
| 16.2 | Static forces | 27 |
| 16.3 | Dynamic forces | 27 |
| 16.4 | Requirements and test method for tips | 27 |
| 16.4.1 | General | 27 |
| 16.4.2 | Friction of tips | 27 |
| 16.4.3 | Durability of tips | 27 |
| 17 | Portable and mobile assistive products | 27 |
| 18 | Surfaces, corners, edges and protruding parts | 29 |

| | | |
|--|--|-----------|
| 19 | Hand held assistive products | 29 |
| 20 | Small parts | 29 |
| 21 | Stability | 29 |
| 22 | Forces in soft tissues of the human body | 29 |
| 23 | Ergonomic principles | 29 |
| 24 | Requirements for information supplied by the manufacturer | 30 |
| 24.1 | General | 30 |
| 24.2 | Instructions for use | 31 |
| 24.2.1 | Pre-sale information | 31 |
| 24.2.2 | User information | 31 |
| 24.2.3 | Service information | 32 |
| 24.3 | Labelling | 32 |
| 25 | Packaging | 33 |
| 26 | Test report | 33 |
| Annex A (informative) European standards for assistive products for persons with a disability produced or currently being developed by CEN/TC 293 | | 34 |
| Annex B (informative) General recommendations | | 36 |
| Annex C (informative) Cognitive impairment | | 43 |
| Annex D (informative) Environmental and consumer related requirements | | 50 |
| Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices | | 56 |
| Bibliography | | 61 |