Test report No.: P - 08 - 015 - MP - PA 041 - E

Technical aids for disabled persons / English Version

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Prüf- und Zertifizierstelle für Medizinprodukte GmbH an der Technischen Universität Berlin

Test institute:	Berlin Cert - Prüf- und Zertifizierstelle für Medizinprodukte GmbH an der Technischen Universität Berlin Dovestr. 6, D-10587 Berlin Tel.: +49(0)30-314-25111, Fax: -23719
Client:	Mobilex A/S, Nörskovvej 1, DK-8660 Skanderborg
Manufacturer:	Mobilex A/S, Nörskovvej 1, DK-8660 Skanderborg
Test sample:	Type / model: Swivel bather / 302022
	Quantity / Identification: 1 / no labelling on the product
	Receipt / condition: 2008-01-14 / new

Handed in later

Test standard:	DIN EN 12182:1999 Technical aids for disabled persons – General requirements and test methods
Annotation:	The numbering corresponds to the applied standard DIN EN 12182: 1999
Accreditation:	Accredited by the "Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten" ZLG-P-946.97.02
Kind of the test:	Partial test (only some requirements of the standard were regarded)
Test period:	2008-01-15 to 2008-02-26
Test location:	Rooms of the test institute
Test result:	The test requirements are fulfilled.

established: 2008-02-26 — Dipl.-Ing. M. Kyslenko

released: 2008-02-26 — Dipl.-Ing. T. Knitter

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-P-946.97.02

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Explanation to Compliance:
Pass: The tested unit was *found to comply* with the requirement.
No: The tested unit does *not comply* with the requirement.
N/A: The tested unit was *not applicable*.

Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
4. General requirements				
4.1 Risk analysis				
The safety of an aid shall be assessed by identifying hazards and estimating the risks associated with them using the procedure specified in EN 1441:1997 supplemented by the requirements of 5.2, 5.4.2, 5.5, 6, 8.2.1, 9.4, 10, 22 and 24.	☒	☐	☐	Risk analysis acc. to DIN EN ISO 14971
4.2 Intended performance and technical documentation				see test report no.: P-08-015-MP-PA021-E, Berlin Cert GmbH
a) An aid shall have sufficient strength and durability to sustain all loads expected during intended use. This shall be confirmed by using, as appropriate, references to relevant clinical and scientific literature, strength and/ or durability calculations, appropriate Standards and test results.	☒	☐	☐	
b) The intended Performance including, if appropriate, strength, durability and tipping stability of an aid shall be described in technical documentation which sets out its functional characteristics, its application(s) and conditions of use.	☒	☐	☐	
c) The technical documentation shall include, if appropriate, references to relevant clinical and scientific literature, any strength and/or life calculations, appropriate standards and test results.	☒	☐	☐	
4.3 Clinical evaluation				
If, as part of the product conformity assessment, the clinical evaluation requires a clinical investigation, the clinical investigation shall conform to the requirements of EN 540:1993.	☐	☐	☒	
4.4 Aids that can be dismantled				
If it is intended that an aid can be dismantled for storage or transportation, it shall not be possible to reassemble the aid in a manner that presents a hazard.	☒	☐	☐	
4.5 Single use fasteners				
If it is intended that an aid can be dismantled for storage or transportation, the fasteners which are loosened or removed to allow this dismantling shall not be single use fasteners.	☒	☐	☐	Single use fasteners include wood screws and self-tapping screws.

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Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
5. Materials				
5.1 Flammability				
Manufacturers shall consider the environments and methods of use to which an aid will be exposed and take appropriate steps to minimize any fire hazard. If an aid is not flame resistant, the manufacturer's information shall describe the precautions necessary to ensure the safety of the User and/or attendant and, where possible, the aid shall be labelled to show that it is not flame resistant. NOTE: Every effort should be made to use products which meet the flammability requirements as it is of particular importance to disabled persons who may not be able to escape from a fire. The use of non-flame retardant materials should be reviewed regularly as there is continuous development in this field.	☐	☐	☒	
5.1.1 Upholstered parts, mattresses, bed bases and bedding				
a) if the manufacturer claims that an aid is resistant to smokers materials it shall comply with the appropriate requirements in 5.1.2, 5.1.3 or 5.1.4;	☐	☐	☒	
b) if the clinical requirements prevent the use of materials which comply with 5.1 .1 a), the reasons shall be included in the technical documentation and the aid shall be supplied with the following:	☐	☐	☒	
1) a warning that it is not flame retardant, placed on the product if possible, and included in the User instructions;	☐	☐	☒	
2) a description of the precautions required to offset the increased risk.	☐	☐	☒	
5.1.2 Upholstered parts				
If the manufacturer claims that the upholstered parts are resistant to ignition by smokers materials, progressive smouldering ignition and flaming ignition shall not occur when the materials used for the upholstered parts of an aid are tested in accordance with EN 1021-1 and EN 1021-2.	☐	☐	☒	
5.1.3 Mattresses and bed bases				
If the manufacturer claims that mattresses and/or bed bases are resistant to ignition by smokers materials, progressive smouldering ignition and flaming ignition shall not occur when treated in accordance with EN 597-1 and EN 597-2.	☐	☐	☒	

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Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
5.1.4 Bedding				
If the manufacturer claims that bedding is resistant to ignition by cigarette, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with EN 32952-1 and EN 32952-2. If the manufacturer claims that bedding is resistant to ignition by small flames , such as those from a match, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with EN 32952-3 and EN 32952-4.	☐	☐	☒	
5.2 Biocompatibility and toxicity				
Materials which come into contact with the human body shall be assessed for biocompatibility using the guidance given in EN 30993-1.The assessment shall take into account the intended use and contact by those involved in user care or transportation and storage of the product.	☐	☐	☐	The result of the assessment shall be incorporated in the risk analysis (see 4.1). Not part of contract
5.3 Contaminants and residues				
5.3.1 Substances which may leak from an aid in intended use and in fault conditions				The requirements do not apply to the body fluids which may be collected in an aid (e.g. stoma care products) but only to those substances which are an integral part of an aid or are needed for its function (e.g. oil and grease).
Substances which may leak from the aid shall either:				
a) be assessed for biocompatibility in accordance with the guidance given in EN 30993-1. The assessment shall take into account the intended use and contact by those involved in user care, transport and Storage;	☐	☐	☒	
or				
b) be provided with protection that minimizes the possibility of such substance becoming a biological hazard. NOTE 1: Substances that can leak include lubricants and hydraulic fluids. NOTE 2: An example of a method of protection from a hazardous substance is where batteries are placed in a container made from acid resistant materiali.	☐	☐	☒	
5.4 Infection and microbiological contamination				
5.4.1 Cleaning and disinfection				
If an aid is intended to be cleaned, the method and suitable cleaning materials shall be described in the information supplied by the manufacturer.	☒	☐	☐	
If an aid is intended to be disinfected, the method and suitable materials shall be described in the information supplied by the manufacturer.	☐	☐	☒	
5.4.2 Animal issues				
Manufacturers shall document the risk assessment of the product according to EN 12442-1:1998 and shall incorporate the results in the risk assessment (see 4.1).	☐	☐	☒	

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Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
5.5 Resistance to erosion				
The risk of corrosion affecting the safety of the user or an attendant shall be assessed in the risk analysis (see 4.1).	☒	☐	☐	
6. Noise and vibration				
If noise and vibration are not part of the intended performance of an aid, hazards and nuisance from noise and vibration, especially as they affect the user or an attendant, shall be assessed in the risk analysis (see 4.1).	☐	☐	☒	
7. Electromagnetic compatibility				
An aid containing electrical or electronic devices/ components shall conform to EN 60601-1-2 and shall, in addition, conform to 7.1 and 7.2.	☐	☐	☒	
7.1 Emissions				
The requirements in EN 61000-3-2 apply, if applicable, as specified in EN 61 000-3-2. The requirements in EN 61000-3-3 apply, if applicable, as specified in EN 61 000-3-3.	☐	☐	☒	
7.2 Immunity				
Aids shall, in addition to the requirements in EN 60601-1-2, clause 36.202.2.1, also be tested with a field strength of 10 V/m (RMS value of the unmodulated carrier) in the frequency range of 800 MHz to 2 GHz. The test shall be performed in accordance with EN 61000-4-3. If, as a result of the application of this test, the aid presents a hazard, or there is any unintentional operation of the aid, the aid fails the test.	☐	☐	☒	
8. Electrical safety				
8.1 General				
a) Electrically powered aids provided with not more than one connection to a particular supply mains and intended to diagnose, treat, or monitor the patient under medical supervision and which make physical or electrical contact with the patient and/or transfer energy to or from the patient and/or detect such energy transfer to or from the patient, shall comply with the requirements for electrical safety of EN 60601-1:1987. All other electrical aids shall comply with the requirements for electrical safety of EN 60335-1 and its appropriate particular requirements.	☐	☐	☒	
b) Aids shall comply with the requirements for electrical safety of Class I or Class II of EN 60335-1 and/or the requirements for electrical safety of Class I, Class II and internally powered equipment of EN 60601-1:1987.	☐	☐	☒	
c) If an aid is intended to be used in both circumstances it shall conform to the requirements of both EN 60601-1:1987 and EN 60335-1.	☐	☐	☒	

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Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
d) If the safety of a person using an aid powered from an electrical supply mains depends upon the continuity of the power supply the aid shall be provided with at least one of the following:				
1) An auxiliary source of power and a means to signal failure of the electrical supply mains; and	☐	☐	☒	
2) A method of non-electrical operation that reduces the risk to users to an acceptable level until they can be removed from the aid, or power is restored together with a means to signal power failure.	☐	☐	☒	
e) If the safety of a patient using an internally powered aid depends upon the power supply a means of determining the state of the power supply shall be provided.	☐	☐	☒	
f) The manufacturer's information shall state the level of protection, as specified in EN 60335-1 or EN 60601-1:1987, as appropriate (See 8.1), and shall describe the intended environment(s) of use and any safety recommendations to avoid hazards due to the ingress of liquids.	☐	☐	☒	
8.2 Battery powered aids				
8.2.1 Battery housings				
a) The need for, and the design of, battery housings shall be based on the risk analysis (see 4.1) and shall identify the hazards and evaluating the risks associated with:				
- leakage of acid and/or other substances from the battery(ies);	☐	☐	☒	
- ventilation of gases generated during charging and/or use;	☐	☐	☒	
- short circuits of the battery(ies);	☐	☐	☒	
b) Housings containing batteries from which gases can escape during charging or discharging, shall be ventilated. NOTE: The Ventilation should minimize the risk of accumulation and ignition of flammable gases.	☐	☐	☒	
c) If a short circuit of a battery could result in a safety hazard, the battery shall be contained in a housing/compartment that prevents the risk of accidentally short circuiting the battery(ies)	☐	☐	☒	
d) Any battery housing/compartment shall collect and store any fluids and/or substances (other than gases) which may leak from the battery(ies) specified by the manufacturer.	☐	☐	☒	
e) The materials used in the manufacture of battery housings shall be resistant to the substances that might leak from the battery(ies) specified by the manufacturer.	☐	☐	☒	

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Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
8.2.2 Connection				
If a safety hazard can develop from the incorrect connection or replacement of a battery, an aid shall be fitted with a means of preventing incorrect polarity.	☐	☐	☒	
8.2.3 Charge level indicator				
If the safety of the user of an aid depends upon power being available from a battery, the aid shall be equipped with a means of indicating the state of the power supply before the critical state at which safety is no longer guaranteed.	☐	☐	☒	
8.3 Circuit protection				
No normative requirement in addition to 8.1.				
8.4 Electronic programmable systems				
Aids which are required to comply with the requirements of EN 60601-1:1987 (8.1 a) and which have an electronic programmable system shall comply with the requirements of EN 60601-1-4.	☐	☐	☒	
8.5 Electrically heated blankets, pads and similar flexible heating appliances				
No normative requirement in addition to 8.1.				
8.6 Aids with skin contact electrodes				
Aids with skin contact electrodes shall comply with the requirements of EN 60601-1:1987 for continuous leakage currents and patient auxiliary currents. NOTE: European standards exist for some types of medical device with skin contact electrodes. In such cases this standard may not apply.	☐	☐	☒	
9. Overflow, spillage, leakage, and ingress of liquids				
9.1 Overflow				
If an aid incorporates a reservoir or liquid storage chamber that may be overfilled or may overflow in the manufacturer's intended use, liquid overflowing from the reservoir or chamber shall not wet electrical insulation and live parts which are liable to be adversely affected by such a liquid, nor shall a safety hazard be created.	☐	☐	☒	
Unless restricted by a marking or by the instructions for use, no safety hazards shall develop if aids are tilted through an angle of 15° from the position of intended use.	☐	☐	☒	
9.2 Spillage				
Aids requiring the use of liquids in the manufacturer's intended use shall be so constructed that spillage do not wet parts which may cause a safety hazard in the product.	☐	☐	☒	

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Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
9.3 Leakage				
Aids shall be so constructed that liquid which might escape in single fault condition does not cause a safety hazard.	☐	☐	☒	
9.4 Ingress of liquids				
The hazards that can be caused by the ingress of liquids to non-electrically powered aids shall be assessed in the risk analysis (see 4.1). NOTE: For requirements for electrically powered aids see 8.1.	☒	☐	☐	
10. Surface temperature				
The risk analysis (see 4.1) shall identify hazards and evaluate the risks associated with the surface temperature of parts which can come into contact with human skin during the intended conditions of use. The risk analysis shall take account of:	☒	☐	☐	
a) the range of ambient temperatures to be expected during the intended use and foreseeable misuse; NOTE: These temperatures could include direct exposure to sunshine, extreme cold, saunas, etc.	☐	☐	☒	
b) temperatures that may result from single fault conditions;	☐	☐	☒	
c) the ergonomic data on acceptable temperatures of touchable surfaces in EN 563;	☐	☐	☒	
d) the use of aids by people with insensitive skin (i.e. cannot feel heat) and/or damaged skin. In this case the maximum temperature shall not exceed 41°C when measured by the methods of test in EN 563. Except that:	☐	☐	☒	
i) if a manufacturer cannot meet this requirement without impairing the intended performance of the aid, each device should be supplied with a warning identifying which surfaces may reach a higher temperature than that specified and a description of the precautions necessary to offset the increased risk;	☐	☐	☒	
and				
ii) if a manufacturer cannot meet the surface temperature requirement the reasons shall be set out in the technical documentation (see 4.2).	☐	☐	☒	
11. Sterility				
11.1 Sterility requirements				
An aid which is labelled "STERILE" shall conform to the requirements of EN 556.	☐	☐	☒	
11.2 Sterilization processes				
Sterilization processes shall be validated and routinely controlled.	☐	☐	☒	

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Test methods and -requirements:	Compliance:			Comments:
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If an aid is sterilized by ethylene oxide the process shall conform to the requirements of EN 550.	☐	☐	☒	
If an aid is sterilized by steam the process shall conform to the requirements of EN 554.	☐	☐	☒	
If an aid is sterilized by irradiation the process shall conform to the requirements of EN 552.	☐	☐	☒	
11.3 Maintenance of sterility in transit				
The packaging shall conform to the requirements of EN 868-1.	☐	☐	☒	
12. Safety of moving parts				
12.1 Unless the intended purpose of an aid, or part of an aid, is to grip, cut, squeeze etc.: or if the intended use cannot be achieved without a hazard such as risk of squeezing (e.g. the elbow or knee flexion of a limb prosthesis) :				
a) any moving parts that constitute a safety hazard shall be provided with guards that can only be removed by the use of a tool;	☐	☐	☒	
or				
b) the gap between exposed parts of an aid that move relative to each other shall be maintained throughout the range of movement at less than the minimum value or more than the maximum value:				(safe distances for children in brackets)
Finger traps less than 8 (4) mm or more than 25 mm	☒	☐	☐	
Foot traps less than 35 (25) mm or more than 120 mm	☒	☐	☐	
Head traps less than 120 (60) mm or more than 300 mm	☐	☐	☒	
Genitalia traps less than 8 mm or more than 75 mm	☐	☐	☒	
or				
c) if cords (ropes), chains and drive belts are used, they shall either be confined so that they cannot run off or jump out of their guiding devices, or a safety hazard shall be prevented by other means. Mechanical means applied for this purpose shall be removable only by the use off a tool;	☐	☐	☒	
or				
d) the aid shall incorporate a control device which initiates the movement when it is operated and stops the movement when it is released (e. g. a spring loaded control device that returns to the stop position when released);	☐	☐	☒	
or				

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Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
e) the aid shall incorporate a means for detecting that a person is in danger of being trapped and automatically activating a means of preventing injury (e.g. by stopping movement);	☐	☐	☒	
or				
f) the aid shall incorporate a control device which initiates a small movement when it is operated and which then stops and requires further initiation for each subsequent increment of movement.	☐	☐	☒	
12.2 If the intended purpose of an aid cannot be met without a hazard such as squeezing, a warning and instructions on how to operate the aid safety shall be provided in the manufacturer's instructions.	☒	☐	☐	
12.3 Parts subject to mechanical wear likely to result in a safety hazard shall be accessible for inspection.	☒	☐	☐	
12.4 If an aid incorporates an emergency stop feature, it shall conform to the requirements of EN 418.	☐	☐	☒	
13. Prevention of traps for parts of the human body				
Holes in and clearances between stationary parts that are accessible to the user and/or attendant during the intended use of an aid shall be:				(safe distances for children in brackets)
Finger traps less than 8 (5) mm or more than 25 (12) mm	☒	☐	☐	
Foot traps less than 35 (25) mm or more than 120 (45) mm	☒	☐	☐	
Head traps less than 120 (60) mm or more than 250 mm	☐	☐	☒	
Genitalia traps less than 8 mm or more than 75 mm	☒	☐	☐	
14. Folding and adjusting mechanisms				
14.1 The mechanisms shall be capable of being securely locked when the aid is in any fixed working configuration.	☒	☐	☐	
14.2 Either				
a) the aid shall incorporate guards to protect the user from trap and/or squeeze hazards;	☐	☐	☒	
or				
b) the gap between exposed parts of an aid that move relative to each other shall be maintained throughout the range of movement at less than the minimum value or more than the maximum value set out in 12.1;	☒	☐	☐	
or				

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Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
c) if the intended purpose of an aid cannot be met without a hazard such as squeezing, a warning and instructions on how to operate the aid safely shall be provided in the manufacturers instructions.	☒	☐	☐	
15. Carrying handles				
15.1 If an aid incorporates carrying handles or grips, they shall not become detached from the aid and there shall not be any permanent distortion, cracking or other evidence of failure when tested as specified in 15.2. After the completion of the test the aid shall operate as intended by the manufacturer.	☐	☐	☒	
15.2 Test method				
If an aid has one handle or grip, or if an aid can readily be carried or lifted by one of a number of handles or grips, determine the force on each handle or grip when it is carried or lifted. If an aid has more than one handle or grip, determine the force on each handle or grip when the aid is carried or lifted in the intended manner. Apply a force to each handle or grip, equal to twice that determined above with a tolerance of +5/-0%, uniformly distributed over a 70 mm f 5 mm length in the center of the handle or grip, avoiding shock. Maintain the force for between 60 s and 70 s. Remove the force and inspect the aid for damage and satisfactory operation.				
16. Aids which support users				
16.1 If an aid is intended to support a disabled person and/or an attendant, no part of the aid shall become detached, exhibit cracking, permanent deformation, loss of stability or any other failure when tested as specified in 16.2. After the test, the aid shall operate as intended by the manufacturer.	☒	☐	☐	
If an aid is intended to fold for transport and/or storage, it shall not fold when tested as specified in 16.2.	☒	☐	☐	
16.2 Test method				
Position the support system in the least favorable position of intended use. Apply a test load, equal to 1,5 times the maximum rated load intended by the manufacturer (including any accessories) with a tolerance of +5/-0 %, to the support surface in the worst case position, in a manner that ensures that there is negligible dynamic loading. Maintain the test load for between 60 s and 70 s. Remove the test load and inspect the aid for damage and satisfactory operation.				Load: F = 1950 N

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Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
17. Portable and mobile aids				
No normative requirement. Normative requirements may be considered for a future development of this standard.				
18. Surfaces, corners and edges				
If not required for the intended function of an aid, all accessible edges, corners and surfaces shall be smooth and be free from burrs and sharp edges.	☒	☐	☐	
If not required for the intended function, aids shall not have projections. Where possible necessary projections shall have protection to prevent injury and/or damage.	☒	☐	☐	
19. Hand held aids				
No normative requirement. Normative requirements may be considered for a future development of this standard.				
20. Grips and other handling devices				
a) If an aid or parts of an aid have a mass of more than 20 kg and need to be handled in the manufacturer's intended use, they shall:				
either				
be provided with suitable handling devices (e.g. handles, lifting eyes);	☐	☐	☒	
or				
the manufacturers information shall indicate the points where aids can be lifted safely and describe how they should be handled during lifting, assembly and/or carrying. If practical, the component parts shall be labelled to indicate where the aid can be lifted safely and/or how it can be handled during assembly and/or carrying.	☐	☐	☒	
b) If an aid is intended by the manufacturer to be portable and it has a mass of more than 20 kg, it shall have one or more carrying-handles suitably placed which enable the aid to be carried by two or more persons.	☐	☐	☒	
21. Forces in soft tissues of the human body				
The hazards that can be caused by forces applied to the soft tissues of the body shall be assessed in the risk analysis (see 4.1).	☐	☐	☒	
22. Ergonomic principles				
An aid shall be designed to the ergonomic principles Set out in EN 614-1 taking into account the Special needs of the disabled Person for whom the device is intended.	☐	☐	☒	
23. Information supplied by the manufacturer				
The information applied to, and supplied with, aids shall conform to EN 1041 together with, but not limited to, the following requirements.	☒	☐	☐	

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Test methods and -requirements:	Compliance:			Comments:
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1) The information shall include advice on which other devices and/or types of device can be used in combination and any precautions or limitations needed to ensure user safety, including the following:	☐	☐	☒	
- warnings and advice about precautions relating to high and /or low temperature surfaces (see 10);	☐	☐	☒	see risk analysis
- warnings and advice about precautions relating to safe distances between moving and stationary parts (see 12 and 13);	☒	☐	☐	
- instructions on how to fold and/or adjust aids and warnings and advice about precautions needed to avoid hazards (see 14);	☒	☐	☐	
- advice on safe lifting and handling (see 20);	☐	☐	☒	
- the level of protection of electrical equipment against the ingress of liquids and advice on the intended environments of use and related safety recommendations (see 9);	☐	☐	☒	
- information about dangerous combinations of devices (e.g. cushions for the prevention of decubitus ulcers often only work on the correct seat surface, spreader bars for slings for hoists are often only suitable for specific products).	☐	☐	☒	
2) The information applied to, and supplied with, aids intended by the manufacturer for use by people with reading difficulties shall be in a form that they can comprehend.	☐	☐	☒	
Aids intended by the manufacturer for use by persons with visual impairment shall be in a tactile (e.g. Braille) or audio form.	☐	☐	☒	
3) The information shall include any maintenance and cleaning instructions.	☒	☐	☐	
4) If the strength and durability of an aid is related to the body mass of a disabled person and/or attendant, the manufacturer's information and labeling shall specify that mass as a limiting value for use.	☒	☐	☐	
5) If an aid is not flame resistant and/or does not comply with the flammability requirements of 5.1 the precautions necessary to ensure the safety of the user and/or attendant and, if possible, the aid shall be labeled to show that it is not flame resistant (see 5.1).	☐	☐	☒	
6) If an aid may be affected by electromagnetic emissions, the information shall include:				
a) advice on the intended environments of use, any environments known to be hazardous, (e.g. close proximity to radio transmitters) and a description of the hazard(s);	☐	☐	☒	
and				

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Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
b) guidance on how to correct any malfunctions.	☐	☐	☒	
7) If an aid is intended to be cleaned, a description of the method and suitable cleaning materials, including any precautions needed to avoid corrosion.	☒	☐	☐	
8) If an aid is intended to be disinfected, a description of the method and suitable materials, including any precautions needed to avoid corrosion.	☐	☐	☒	
9) If an aid can create a noise hazard, warnings and advice about precautions relating to high output sound levels. NOTE 1: Most guidance require that the information is in one or more of their official languages. NOTE 2: The guidance document ISO/IEC Guide 37: Instructions for consumer products should be considered when preparing this information. NOTE 3: Manufacturers are recommended to present their information in separate parts that cover use, prescription, technical and/or paramedical aspects and medical aspects.	☐	☐	☒	
24. Packaging				
The hazards that can be caused by inadequate protective packaging shall be assessed in the risk analysis (see 4.1).	☒	☐	☐	

Submitted documents:	
User manual	Issue: 2008/02
Risk analysis	Date: 20.02.2008

Test equipment:	see test report no.: P-08-015-MP-PA021-E

Technical data:	see test report no.: P-08-015-MP-PA021-E

Notes: