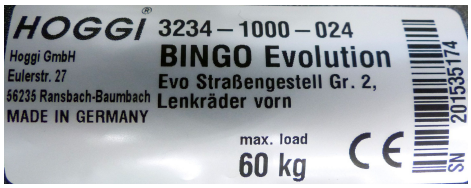
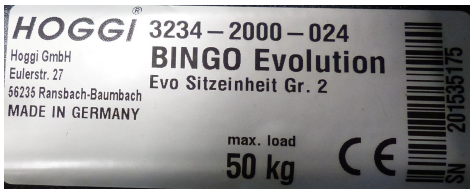
Test report No.: PB - 15 - 217 - MP - PA137 - E - N1

DIN EN 12182 Assistive products for persons with disability – General requirements and test methods / English Version

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:	HOGGI GmbH, Taunusstr. 17, D-56235 Ransbach-Baumbach
Manufacturer:	HOGGI GmbH, Taunusstr. 17, D-56235 Ransbach-Baumbach
Test sample:	Type / model: Reha-Buggy / BINGO Evolution Gr.2
	Quantity/ identification: 1 / 3234-1000-024 SN: 201535174 chassis 3234-2000-024 SN: 201535175 seat unit
	Receipt / condition: 2015-09-18 / new





Test standard:	DIN EN 12182 Assistive products for persons with disability – General requirements and test methods
Annotiation:	The numbering corresponds to the applied standard DIN EN 12182:2012
Kind of test:	Complete test, based on P-10-339-MP, see page 28
Test period:	2015-09-21 to 2015-10-07
Test location:	Rooms of the test institute
Test result:	The test requirements are fulfilled except for point 6.4. included in the test report P-10-339-MP-PA129-E-N1; see page 28 for details

established: 2015-10-07

Dipl.-Ing. (FH) F. Aßmann
Test Engineer

released: 2015-10-07

Digital unterschrieben von Salar Fallah
Datum: 2015.10.07 11:25:08 +02'00'

Dipl.-Ing. (FH) S. Fallah
Test Engineer

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 assistive product shall be assessed by identifying hazards and estimating the risks associated with them using the procedures specified in EN ISO 14971. When using an assistive product in combination with a device that is not a medical device the device shall behave in a safe way regarding the MDD as a system.	☒	☐	☐	
4.2 Intended performance and technical documentation				
a) An assistive product shall have sufficient strength and durability to sustain all loads expected during its intended use. This shall be confirmed by using, as appropriate, references to relevant clinical and scientific literature in addition to requirements in this standard, strength and/or durability calculations, appropriate test standards and their test results.	☒	☐	☐	
b) The intended performance including, if appropriate, strength, durability and tipping stability of an assistive product 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, conformity with appropriate test standards and their test results.	☒	☐	☐	
4.3 Clinical evaluation and investigation				
A clinical evaluation shall be done for all assistive products. 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 ISO 14155-1 and EN ISO 14155-2. A clinical evaluation shall always be done before performing a clinical investigation.	☒	☐	☐	
4.4 Assistive products that can be dismantled				
If it is intended that an assistive product can be dismantled for storage or transportation, it shall not be possible to reassemble the assistive product in a manner that presents a hazard.	☒	☐	☐	
4.5 Fasteners				
If it is intended that an assistive product can be dismantled for storage or transportation, the fasteners which are loosened or removed to allow this dismantling	☒	☐	☐	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
shall not be single use fasteners. Example: Single use fasteners include wood screws and self-tapping screws.				
4.6 Mass limits				
The user mass limit and maximum rated load shall be declared by the manufacturer.	☒	☐	☐	
4.7 Immobilising means				
If the movement of an assistive product or of any of its parts constitutes a risk for the user or a nearby person, there shall be immobilising means that provide control of the speed and/or prevent any undesired movement.	☒	☐	☐	
4.8 Design requirements in relation to persons with cognitive impairment				
a) Persons with cognitive impairment shall be considered potential users of all assistive products;	☒	☐	☐	
b) Cognitive impairment aspects shall, as far as possible, be considered in the design, performance and use of all assistive products;	☒	☐	☐	
c) The result of such considerations shall be described in the producer´s technical documentation;	☒	☐	☐	
d) An assistive product may be used not only by whom it is primarily intended, but also by an assistant. Risk management shall include all involved persons.	☒	☐	☐	
5. Materials				
5.1 General				
Manufacturers should, wherever possible, use materials that can be recycled for further use.	☒	☐	☐	
5.2 Flammability				
5.2.1 General				
Manufacturers shall consider the environments and methods of use to which an assistive product or any materials that are usually used in combination with this assistive product, will be exposed and take appropriate steps to minimize any fire hazard.	☒	☐	☐	
The manufacturer shall include a warning in the instructions for use about safe combinations of flame resistant and non flame resistant materials.	☒	☐	☐	
5.2.2 Upholstered parts, mattresses, bed bases and bedding				
a) If the manufacturer claims that an assistive product is resistant to ignition by a cigarette or a small flame it shall comply with the appropriate requirements in 5.2.3, 5.2.4 or 5.2.5;	☒	☐	☐	
or				

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
b) if the clinical requirements prevent the use of materials which comply with 5.2.2 a), the reasons shall be included in the technical documentation and the assistive product shall be supplied with the following:	☐	☐	☒	
1) warning that it is not flame retardant, placed on the product if possible, and included in the instructions for use;	☐	☐	☒	
2) a description of the precautions required to offset the increased risk..	☐	☐	☒	
5.2.3 Upholstered parts				
If the manufacturer claims that the upholstered parts are resistant to ignition by a cigarette or a small flame, progressive smouldering ignition and flaming ignition shall not occur when the materials used for the upholstered parts of an assistive product are tested in accordance with EN 1021-1 and EN 1021-2.	☒	☐	☐	
5.2.4 Mattresses and bed bases				
If the manufacturer claims that mattresses and/or bed bases are resistant to ignition by a cigarette or a small flame, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with EN 597-1 and EN 597-2.	☐	☐	☒	
5.2.5 Bedding				
If the manufacturer claims that bedding is resistant to ignition by a cigarette or a small flame, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with EN ISO 12952-1 and EN ISO 12952-2.	☐	☐	☒	
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 ISO 12952-2.	☐	☐	☒	
5.2.6 Moulded parts				
If the manufacturer claims that a plastic moulded part is resistant to ignition by cigarettes, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with FV-1 of EN 60695-11-10 or better. If the product is of a type that the user normally (by himself) cannot escape from or detect as a dangerous situation it shall be FV-0. If the manufacturer claims that plastic moulded parts are 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 60695-11-10.	☐	☐	☒	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
5.3 Biocompatibility and toxicity				
Materials which come into contact with the human body shall be assessed for biocompatibility using the guidance in EN ISO 10993-1 and shall fulfil the following requirements. 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 assistive products shall be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the assistive product. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction and other substances of very high concern (SVHCs). The assessment should follow the guidance given in Annex D. The result of the assessment shall be incorporated in the risk analysis (see 4.1).	☒	☐	☐	
5.4 Contaminants and residues				
The requirements given in 5.4.2 do not apply to the body fluids which may be collected in an assistive product (e.g. stomacare products) but only to those substances which are an integral part of an assistive product or are needed for its function (e.g. oil and grease).				
5.4.2 Substances which may leak from an assistive product in intended use and in fault conditions shall either:				
a) be assessed for biocompatibility in accordance with the guidance given in EN ISO 10993-1; 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 substances 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 material.	☐	☐	☒	
5.5 Infection and microbiological contamination				
5.5.1 Cleaning and disinfection				
If an assistive product is intended to be cleaned, the method and suitable cleaning materials shall be described in the information supplied by the manufacturer.	☒	☐	☐	
If an assistive product is intended to be disinfected, the method and suitable materials shall be described in	☒	☐	☐	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
the information supplied by the manufacturer.				
If an assistive product is intended to be cleaned by automatic washing systems or hand held jet stream/steam washing the details of the procedure, such as temperature, pressure, flow and pH value of cleaning/rinsing solution shall be described in the instructions for use. Where practicable, the assistive product shall be labelled with appropriate symbols to represent the method of cleaning. See examples of labelling and an example of test of machine washable assistive products in B.5.5.1.	☐	☐	☒	
5.5.2 Animal tissue				
Where a device has been manufactured utilising tissues of animal origin or their derivatives, a risk assessment shall be performed and documented according to EN ISO 22442-1.	☐	☐	☒	
5.6 Resistance to corrosion				
The risk of corrosion affecting the safety of the user or an assistant shall be assessed in the risk analysis (see 4.1).	☒	☐	☐	
6. Emitted sound and vibration				
6.1 Noise and vibration				
If noise and vibration are not part of the intended performance of an assistive product, hazards and nuisance from noise and vibration shall be assessed in the risk analysis (see 4.1).	☒	☐	☐	
Measurements for noise of power operated assistive products shall be done in accordance with EN ISO 3746, and the result of the measurement shall be recorded in the pre sale information and in the instructions for use.	☐	☐	☒	
6.2 Sound levels and frequencies of audible warning devices				
The frequency shall be within the range 500 Hz to 16 000 Hz and should be within the range 500 Hz and 3 000 Hz.Sound levels shall be at least 65 dB(A) for audible alarms, and should be at least 75 dB(A). The alarm or feedback signal shall be distinguished from the noise of the product itself either by frequency or sound level. Measurements shall be made in accordance with EN ISO 3746.	☐	☐	☒	
6.3 Feedback				
All user commands shall have some kind of feedback e.g audible, visible or tactile that clearly indicates that a command has been given and/or effectuated. The feedback shall be accessible for all relevant operators. The sound level for a feedback or speech system shall	☐	☐	☒	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
be within 50-80 dB(A). Measurements shall be done in accordance with EN ISO 3746.				
7. Electromagnetic compatibility				
7.1 General				
An assistive product containing electrical or electronic devices/components shall conform to EN 60601-1-2 and shall, in addition, conform to 7.2, 7.3 and 7.4.	☐	☐	☒	
7.2 Emissions				
When tested in CISPR 11, the equipment shall meet the radiated emissions limits specified in CISPR 11 for group 1, class B equipment specified in CISPR 11. The requirements in EN 61000-3-2 apply, if applicable, as specified in EN 61000-3-2. The requirements in EN 61000-3-3 apply, if applicable, as specified in EN 61000-3-3.	☐	☐	☒	
7.3 Immunity				
Assistive products shall, in addition to the requirements in EN 60601-1-2:2007, subclause 36.202.2.1, also be tested with a field strength of 20 V/m (RMS value of the unmodulated carrier) in the frequency range of 800 MHz to 2,5 GHz. The test shall be performed in accordance with EN 61000-4-3. If, as a result of the application of this test, the assistive product presents a hazard, or there is any unintentional operation of the assistive product, the assistive product fails the test.	☐	☐	☒	
7.4 Power frequency magnetic field immunity				
When the equipment is tested in accordance with EN 61000-4-8 using test level 4, at 50 Hz and 60 Hz: a) the equipment shall behave safe in the presence of the applied field; b) electrically powered devices or electrically moved functions shall not make any unintentional operation in the presence of the applied field. Perform the continuous field immunity test specified in EN 61000-4-8 on the equipment as table-top equipment. Test the equipment for not less than one minute for each orientation of the applied field.	☐	☐	☒	
8. Electrical safety				
8.1 General				
Assistive products shall comply for electrical safety to the requirements of applicable standards according to guidance given in Table 1. Homecare electrical equipments connected to mains shall be of class II (double isolated) except if the use is in wet areas where	☐	☐	☒	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
the requirement shall be class I (earth). Hospital based electrical equipments connected to mains shall be of class I (earth).				
8.2 Electrical systems				
An electrical system can consist of several components, each tested to different standards. For the applicability of standards for components of electrical systems see Table 1 (s.S.18).				
8.3 Continuity of power supply				
If the safety of a person using an assistive product powered from electrical supply mains depends upon the continuity of the power supply, the assistive product shall be provided with a level of protection as follows:				
- If the (intended) user is not able to react reasonably or timely, an auxiliary source of power, which – in case of discontinuity of the power supply – is automatically and timely connected to the assistive product and a means to signal to the assistant that a discontinuity of the power supply has occurred; the auxiliary source of power shall provide sufficient power to allow timely reaction;	☐	☐	☒	
- If the (intended) user is able to react reasonably and timely, an auxiliary source of power and a means to signal to the user that a discontinuity of the power supply has occurred; the auxiliary power source shall provide sufficient power to allow timely reaction;	☐	☐	☒	
- If it is feasible, a method of non-electrical operation that reduces the risk to users to an acceptable level until they can be removed from the assistive product, or power is restored together with a means to signal power failure to the operator who is intended for such emergency operations.	☐	☐	☒	
If there is a battery backup when there is a failure in the mains, this should start to function as fast as possible and have a performance time long enough to bring the user to a safe place or position.	☐	☐	☒	
If the safety of a person using an internally powered assistive product depends upon the continuity of the power supply, a means of informing the user of a critical charge of the power supply shall be provided. At the time of reaching the critical charge, either an auxiliary source of sufficient power or a sufficient reserve charge of the internal power supply shall be available to allow timely reaction.	☐	☐	☒	
8.4 Battery powered assistive products				
8.4.1 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	☐	☐	☒	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
with:				
1) leakage of acid and/or other substances from the battery(ies);	☐	☐	☒	
2) ventilation of gases generated during charging and/or use;	☐	☐	☒	
3) short circuits of the battery(ies);	☐	☐	☒	
b) Housings containing batteries from which gases can escape during charging or discharging shall be ventilated.	☐	☐	☒	
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.	☐	☐	☒	
8.4.2 Connection				
If a safety hazard can develop from the incorrect connection or replacement of a battery, an assistive product shall be fitted with a means of preventing incorrect polarity.	☐	☐	☒	
8.4.3 Charge level indicator				
If the safety of a person using an internally powered assistive product depends upon the power supply, a means of informing the user of the state of the charge of the power supply shall be provided. At the time of indicating the critical charge, sufficient reserve charge of the internal power supply shall be available to allow timely reaction.	☐	☐	☒	
There shall be some kind of indication of the status of the battery that is adapted to all kind of users, e.g. persons with a visual or a hearing disability.	☐	☐	☒	
8.5 Circuit protection				
A fuse or over-current release shall be provided in each supply lead for class I equipment and for class II equipment having a functional earth connection, and in at least one supply lead for other single-phase class II equipment, except that:	☐	☐	☒	
- For permanently installed equipment, the neutral conductor shall not be fused.				
- If examination shows that two means of protection are present between all parts of opposite polarity within the mains part, and between all parts of the mains part and				

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
earth, then the fuses or over-current releases may be omitted. These insulation requirements shall be continued up to and within any component. The effect of short-circuit fault conditions in other circuits shall be considered before eliminating fuses or over-current releases.				
A protective earth conductor shall not incorporate a fuse or over-current release.	☐	☐	☒	
Protective devices shall have adequate breaking capacity to interrupt the maximum fault current (including short-circuit current) which can flow.	☐	☐	☒	
If fuses complying with EN 60127 are used and the prospective short-circuit current exceeds 35 A or 10 times the current rating of the fuse, whichever is greater, the fuses should have high breaking capacity (1 500 A).	☐	☐	☒	
a) Thermal cut-outs and over-current releases with automatic resetting shall not be used in assistive products if their use could result in a hazardous situation by such resetting. Compliance is checked by inspection of the risk management file.	☐	☐	☒	
b) Thermal cut-outs with a safety function that have to be reset by a soldering operation that can affect the operating value shall not be fitted in assistive products. Compliance is checked by inspection of the design documentation and the risk management file.	☐	☐	☒	
c) In equipment where a failure of a thermostat could constitute a hazard, an independent non-self-resetting thermal cut-out shall additionally be provided. The temperature of operation of the additional device shall be outside that attainable at the extreme setting of the normal control device but shall be within the safe temperature limit for its intended function. Compliance is checked by inspection of the design documentation and the risk management file.	☐	☐	☒	
d) Capacitors or other spark-suppression devices of equipment shall not be connected between the contacts of thermal cut-outs. Compliance is checked by inspection.	☐	☐	☒	
e) Capacitors or other spark-suppression devices of equipment shall not be connected between the contacts of thermal cut-outs. Compliance is checked by inspection.	☐	☐	☒	
f) The use of a thermal cut-out or over-current release in the design shall not affect the safety of the equipment. Compliance is checked by inspection and, if applicable, by the following tests. Verify compliance of Positive Temperature Coefficient devices (PTCs) with EN 60730-1 as applicable. Thermal cut-outs and over-current releases shall be tested by	☐	☐	☒	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
operating the equipment. Self-resetting thermal cut-out and self-resetting over-current releases including circuits that perform equivalent functions (other than PTCs) shall be caused to operate 200 times unless approved to the appropriate IEC component standard. Manual reset thermal cut-outs and over-current releases shall be caused to operate 10 times if they are not approved to the appropriate IEC component standard. Thermal protection devices shall comply with the appropriate IEC component standards or the manufacturer shall provide adequate data to demonstrate the reliability of the component to perform its safety-related function. Thermal protection devices can be tested separately from medical electrical equipment where engineering judgement indicates that doing so would not impact the test results.				
g) Equipment that incorporates a fluid filled container having heating facilities shall be provided with a protection device to safeguard against overheating in the event of the heater being switched on with the container empty. An unacceptable risk shall not occur from overheating. Compliance is checked by operating the relevant equipment with an empty container until the protection device activates.	☐	☐	☒	
h) Equipment that incorporates tubular heating elements shall have protection against overheating in both leads where a conductive connection to earth could result in overheating.	☐	☐	☒	
An internal electrical power source in equipment shall be provided with an appropriately rated device for protection against fire hazard caused by excessive currents if the cross-sectional area and layout of the internal wiring or the rating of connected components may give rise to a fire hazard in case of a short circuit.	☐	☐	☒	
8.6 Electronic programmable systems				
Assistive products which are required to comply with the requirements of EN 60601-1 and which have an electronic programmable system shall also comply with the requirements of EN 62304.	☐	☐	☒	
8.7 Electrically heated blankets, pads and similar flexible heating appliances				
An electrically heated blanket, pad or similar flexible heating appliances shall fulfil the requirements in EN 80601-2-35.	☐	☐	☒	
8.8 Assistive products with skin contact electrodes				
Assistive products with skin contact electrodes shall comply with the requirements of EN 60601-1 for continuous leakage currents and patient auxiliary currents. Note: European standards exist for some types of	☐	☐	☒	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
medical assistive products with skin contact electrodes. In such cases this standard may not apply..				
8.9 Ingress of liquids				
Enclosures shall be classified according to the degree of protection against harmful ingress of water as detailed in EN 60529.	☐	☐	☒	
Compliance is checked by tests in EN 60529 placed in the least favourable position for normal use.	☐	☐	☒	
For equipment not in contact with water or body fluids, it shall be protected to IP X1.	☐	☐	☒	
For equipment that is in contact with water or body fluids it shall at least be protected to IP X4.	☐	☐	☒	
9. Overflow, spillage, leakage, and ingress of liquids				
9.1 Overflow				
9.1.1 Requirements				
If an assistive product 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 assistive products are tilted through an angle that is 15º greater then the maximum inclination that can occur during intended use.	☐	☐	☒	
9.1.2 Test method				
Fill the reservoir to the maximum level specified by the manufacturer and, if possible, add further liquid equal to 15% of the capacity of the reservoir or until the reservoir is full. Tilt the assistive product through an angle of (15+ 1)ºC in each direction(s) starting from the position of the manufacturer's intended use or the maximum angle of intended use, whichever is the most severe. If necessary, refill the reservoir between tests. If the working position is a specified range the (15+ 1) ºC shall add to the extreme position of this range. These procedures shall not wet parts of the assistive product that will cause a hazard. In particular, an assistive product shall show no signs of wetting of un-insulated live parts or electrical insulation of parts which may cause a safety hazard. For electrical insulation, in case of doubt, the assistive product shall be subjected to the dielectric strength test as described in EN 60601-1.	☐	☐	☒	
9.2 Spillage				
9.2.1 Requirements				
Assistive products requiring the use of liquids for the manufacturer's intended use shall be so constructed				

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
that spillage does not wet parts which may cause a safety hazard in the product.	☐	☐	☒	
9.2.2 Test method				
Position the equipment as in the manufacturer's intended use. Pour (200+ 5) ml of water steadily on an arbitrary point on the top surface of the assistive product. After the test, the assistive product shall function as specified by the manufacturer.	☐	☐	☒	
9.3 Leakage				
Assistive products shall be so constructed that liquid which might escape in single fault condition does not cause a safety hazard.	☐	☐	☒	
9.4 Ingress of liquids				
9.4.1 Requirements				
If liquid unintentionally can come into an enclosure there shall be a way for the liquid to get out of the enclosure, or the liquid shall not cause any harm. The hazards that can be caused by the ingress of liquids to non-electrically powered assistive products shall be assessed in the risk analysis (see 4.1).	☐	☐	☒	
9.4.2 Test method				
Test if the liquid can get out of the enclosure by tilting it 10 degrees to each direction. If there still is liquid in the enclosure test the equipment to check if it fails to work, or if the liquid is likely to cause any harm.	☐	☐	☒	
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 ISO 13732-1;	☒	☐	☐	
d) the use of assistive products 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 ISO 13732-1; except that:	☒	☐	☐	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
1) if a manufacturer cannot meet this requirement without impairing the intended performance of the assistive product, each assistive product 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				
2) 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 assistive product which is labelled "sterile" shall conform to the requirements of EN 556-1.	☐	☐	☒	
11.2 Sterilization processes				
Sterilization processes shall be validated and routinely controlled.	☐	☐	☒	
If an assistive product is sterilized by ethylene oxide the process shall conform to the requirements of EN ISO 11135-1.	☐	☐	☒	
If an assistive product is sterilized by steam the process shall conform to the requirements of EN ISO 25424.	☐	☐	☒	
If an assistive product is sterilized by radiation the process shall conform to the requirements of EN ISO 11137-1 and EN ISO 11137-2.	☐	☐	☒	
11.3 Maintenance of sterility in transit				
The packaging shall conform to the requirements of EN ISO 11607-1.	☐	☐	☒	
12. Safety of moving parts				
12.1 Squeezing				
Unless the intended purpose of an assistive product, or part of an assistive product, 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				

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
b) the gap between exposed parts of an assistive product 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:				The values in brackets apply to children
Finger traps, < 8 (4) mm or > 25 mm	☒	☐	☐	
Foot traps, < 35 (25) mm or > 120 mm	☒	☐	☐	
Head traps, < 120 (60) mm or > 300 mm	☒	☐	☐	
Genitalia traps, < 8 mm or > 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 of a tool;	☐	☐	☒	
or				
d) the assistive product 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				
e) the assistive product 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 the movement).;	☐	☐	☒	
For moving parts that can cause squeezing, manufacturers shall take into consideration what part/ parts of the body that are at risk. The user/user group has to be specified, so that correct safety distances can be applied.	☒	☐	☐	
12.2 Mechanical wear				
Parts subject to mechanical wear likely to result in a safety hazard shall be accessible for inspection.	☒	☐	☐	
12.3 Emergency stopping functions				
If there is a risk for the user to be squeezed or a single fault appearing that might create a safety hazard there shall be an emergency stop as specified in EN ISO 13850 together with the following requirements:	☐	☐	☒	
- The assistive product shall be designed to prevent accidental damage or stopping movements.	☐	☐	☒	
- The user shall be able to reach the emergency stop easily, and stop the dangerous situation within one action.	☐	☐	☒	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
- The stopping device shall maintain the equipment in a safe position, but not interfere with other critical functions.	☐	☐	☒	
- The emergency stopping device shall maintain the assistive product in a stopped position until it is realesed by a designated procedure	☐	☐	☒	
- The designated procedure for the release of the emergency stop shall require two independent actions.	☐	☐	☒	
- A safe stopping distance shall be considered in the risk analyses.	☐	☐	☒	
13. Prevention of traps for parts of the human body				
13.1 Holes and clearances				
Holes in, and clearances between stationary parts that are accessible to the user and/or assistant during the intended use of an assistive product shall be as specified in the following table:				The values in brackets apply to children
Finger traps, < 8 (5) mm or > 25 (12) mm	☒	☐	☐	
Foot traps, < 35 (25) mm or > 100 (45) mm	☒	☐	☐	
Head traps, < 120 (60) mm or > 250 mm	☒	☐	☐	
Genitalia traps, < 8 mm or > 75 mm	☒	☐	☐	
If the intended purpose of an assistive product cannot be met without a hazard caused by the size of holes and the clearance between stationary parts, a warning and instructions on how to operate the assistive product safely shall be provided in the instructions for use.	☐	☐	☒	
For stationary parts that can cause a trap, manufacturers shall take in consideration what part/ parts of the body that are at risk. The user/user group has to be specified, so that correct safety distances can be applied. The design of parts that confine a hole or clearance shall take into consideration the forces that can be applied in normal use.	☐	☐	☒	
On holes with the shape of a keyhole or V-shaped openings the lower limit shall not apply. When inspecting the assistive product for traps for body parts any flexibility/elasticity of adjacent parts shall be taken into account.				
13.2 V-shaped openings				
The risk of entrapment in V-shaped openings shall be assessed by the manufacturer. Particular guidance can be found in B.13.2.	☐	☐	☒	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
14. Folding and adjusting mechanisms				
14.1 General				
Folding and adjusting mechanisms may cause a hazard if parts of the body can enter a gap between parts and be trapped when the gap is closed. If an assistive product incorporates folding and/or adjusting mechanisms it shall conform to 14.2 and 14.3.	☒	☐	☐	
14.2 Locking mechanisms				
The mechanisms shall be capable of being securely locked when the assistive product is in any fixed working configuration. It shall also be capable of being securely locked when folded if it constitutes a risk for the user or assistant. The product shall fold in a safe manner.	☒	☐	☐	
14.3 Guards				
Either:				
a) the assistive product shall incorporate means to protect the user from trap and/or squeeze hazards;	☒	☐	☐	
or				
b) the gap between exposed parts of an assistive product 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 Table 2;	☒	☐	☐	
or				
c) if the intended purpose of an assistive product cannot be met without a hazard such as squeezing, a warning and instructions on how to operate the assistive product safely shall be provided in the instructions for use.	☐	☐	☒	
The design of a guard shall take into consideration the forces that can be applied in normal use.				
15. Carrying handles				
15.1 General				
Manufacturers should note that national and other requirements may demand test loads in excess of the following. If an assistive product is intended by the manufacturer to be portable and it has a mass of more than 10 kg, it shall have one or more carrying-handles suitably placed which enable the assistive product to be carried by two or more persons. If an assistive product or parts of an assistive product have a mass of more than 10 kg and need to be handled in the manufacturer's intended use, they shall either:				
a) be provided with suitable handling devices (e.g. handles, lifting eyes);	☐	☐	☒	
or				

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
b) the instructions for use shall indicate the points where assistive products 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 assistive product can be lifted safely and/or how it can be handled during assembly and/or carrying.	☐	☐	☒	
15.2 Requirements				
If an assistive product incorporates carrying handles or grips, they shall not become detached from the assistive product and there shall not be any permanent distortion, cracking or other evidence of failure when tested as specified in 15.3. After the completion of the test the assistive product shall operate as intended by the manufacturer.	☐	☐	☒	
15.3 Test method				
If an assistive product has one handle or grip, or if an assistive product can be readily 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 assistive product has more than one handle or grip, determine the force on each handle or grip when the assistive product is carried or lifted in the intended manner. On each handle or grip determine the force necessary to carry the assistive product in the intended manner with a tolerance of + 5 %. If there is more than one intended manner determine the highest force. Restrain the assistive product from being lifted or moved during the following test. Apply a force to each handle or grip, equal to twice that determined above with a tolerance of + 5 %, uniformly distributed over a 70 mm ± 5 mm length in the centre of the handle or grip, avoiding shock (see Figure 1). Maintain the force for between 60 s and 70 s. Remove the force and the restraints and inspect the assistive product for damage and satisfactory operation.	☐	☐	☒	
16. Assistive products which support or suspend users				
16.1 General				
If an assistive product is intended to support or suspend a person with a disability and/or an assistant or load, no part of the assistive product shall become detached, exhibit cracking, permanent deformation, loss of stability or any other failure when tested as specified in 16.2 and 16.3. After the test, the assistive product shall operate as intended by the manufacturer. If an assistive product is intended to fold for transport and/or storage, it shall not fold when tested as specified in 16.2 and 16.3.	☒	☐	☐	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
16.2 Static forces				
Position the support or suspend system in the least favourable position of intended use. Apply a test load to the support surface in the worst case position and in a manner that ensures that there is negligible dynamic loading. The test load is equal to the maximum rated load, including any accessories, specified by the manufacturer, with a tolerance of + 5 %, multiplied by a safety factor. The safety factor is equal to 1,5 for a supported system. For a suspended system, the safety factor is as specified in Table 4. Maintain the test load for between 60 s and 70 s. Remove the test load and inspect the assistive product for damage. The product shall still function normally.	☒	☐	☐	Test load: F = 883 N
16.3 Dynamic forces				
Apply a test load equal to the maximum rated load intended by the manufacturer for a supported and suspended system (including any accessories) with a tolerance of + 5 %, to the support surface in the worst case position (in a manner that ensures that there is negligible dynamic loading). The test cycle shall be calculated from normal use and life time of the product.	☒	☐	☐	Test load: F = 491 N see submitted documents
16.4 Requirements and test method for tips				
16.4.1 General				
If the assistive product is provided with a tip that carries or supports the user, it shall be safe in its use and environment. Examples: A shower chair, a crutch.	☐	☐	☒	
16.4.2 Friction of tips				
For safety of friction of tips for any assistive product, using a tip, intended to be placed on a floor, table or on the ground, the relevant parts of EN ISO 24415-1 shall be used.	☐	☐	☒	
16.4.3 Durability of tips				
For durability of tips for any assistive product, using a tip, intended to be placed on a floor, table or on the ground, the relevant parts of ISO 24415-2 shall be used.	☐	☐	☒	
17. Portable and mobile assistive products				
A portable assistive product or any of its parts that is portable shall withstand the stresses caused by a free fall from the height indicated in Table 5 onto a hard surface. Compliance is checked by the following test: The sample to be tested, with the maximum recommended rated load in place, is lifted to a height as indicated in Table 5 above a 50 mm ± 5 mm thick hardwood board (for example, > 600 kg/m3) that lies flat on a concrete floor or a similar rigid base. The	☒	☐	☐	See submitted documents

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
dimensions of the board shall be at least those of the footprint of the sample tested. The sample is dropped three times from each orientation in which it may be placed during the intended use. After the test, the equipment shall be inspected for any damage, which results in an unacceptable risk or loss of function. Any such damage constitutes a failure.				
A mobile assistive product and any of its parts that is mobile shall withstand the stresses caused by rough handling and movement and shall not result in an unacceptable risk or loss of function. The sample is tested in the intended transport position with maximum rated load in place and in the most adverse condition permitted for the intended use. Compliance is checked by the following tests:	☒	☐	☐	
a) Ascending step shock: The sample is pushed three times in its intended direction of travel at a speed of 0,4 m/s ± 0,1 m/s or, for motor driven mobile assistive product, the maximum speed capable of being maintained, against an ascending hardwood step obstruction with vertical face of 40 mm that is rigidly attached to an otherwise flat floor. The direction of movement is perpendicular to the face of the obstacle. The sample does not need to go over the 40 mm obstruction.	☒	☐	☐	
b) Descending step shock: The sample is pushed three times in its intended direction of travel at a speed of 0,4 m/s ± 0,1 m/s or, for a motor driven mobile assistive product, the maximum speed capable of being maintained, in order to fall over a descending vertical step having a height of 40 mm affixed flat on a rigid base (e.g. concrete). The direction of movement is perpendicular to the face of the descending step. During performance of the descending step shock test, if a part other than a wheel comes in contact with the obstruction before one of the wheels touches the ground, the equipment continues to be pushed until it has fully descended.	☒	☐	☐	
c) Door frame shock: The sample is moved three times in its normal direction of travel at a speed of 0,4 m/s ± 0,1 m/s, or, for a motor driven mobile assistive product, the maximum speed capable of being maintained, against a hardwood vertical obstacle having suitable dimensions that is affixed to a vertical rigid support (e.g. concrete). The height of the vertical obstacle must be at the height of the equipment's contact point(s). The direction of movement is perpendicular to the face of the obstacle.	☒	☐	☐	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
After each test, the sample shall be inspected for any damage, which results in an unacceptable risk or loss of function. Any such damage constitutes a failure.				
18. Surfaces, corners, edges and protruding parts				
If not required for the intended function of an assistive product, all accessible edges, corners and surfaces shall be smooth and be free from burrs and sharp edges.	☒	☐	☐	
If not required for the intended function, assistive products shall not have protruding parts. Where possible, necessary protruding parts shall have protection to prevent injury and/or damage.	☒	☐	☐	
19. Hand held assistive products				
An assistive product and any of its parts that is hand-held during its intended use shall not result in an unacceptable risk or loss of function as a result of a free fall. Compliance is checked by the following tests: The sample to be tested, with the maximum rated load in place, is allowed to fall freely once from each of three different starting orientations encountered during the intended use from the height at which the assistive product is used (as defined by the manufacturer specified in the accompanying documents), or from a height of 1 m, whichever is greater, onto a 50 mm ± 5 mm thick hardwood board (hardwood > 600 kg/m³) lying flat on a concrete or a similar rigid base. After the test, the hand-held assistive product and any of its parts that are hand-held during their intended use shall not result in an unacceptable risk or loss of function.	☐	☐	☒	
20. Small parts				
Assistive products and their parts intended to be used by small children shall not be of a size where they can create a danger to small children being choked.	☒	☐	☐	
21. Stability				
For safety of stability of any assistive product, other than fixed or handheld, intended to be placed on a floor, table or on the ground, the relevant parts of EN 60601-1:2006 including parts 9.4.1, 9.4.2, 9.4.3 shall be used.	☐	☐	☒	
22. 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).	☒	☐	☐	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
23. Ergonomic principles				
An assistive product shall be designed to the ergonomic principles set out in EN 614-1 taking into account the special needs of the person with a disability for whom the assistive product is intended. An assistive product may be used not only by whom it is primarily intended for, but also by an assisting person. The ergonomic principles set out in EN 614-1 shall apply to all involved persons. Grips, handles and pedals shall suit the functional anatomy of the user, according to the intended use.	☒	☐	☐	
Grips, handles and pedals shall meet with the following requirements:				
a) the distance between any handle (part intended to be grabbed) requiring an operating force of more than 10 N and any construction part of the assistive product shall not be less than 35 mm;	☒	☐	☐	
b) the distance between any upper surface of a pedal (in its operating position) and any other part of the assistive product shall have a vertical toe clearance of not less than 75 mm;	☒	☐	☐	
c) the diameter of any operating handles and/or knobs requiring an operating force of more than 10 N shall be between19 mm and 43 mm;	☒	☐	☐	
d) for assistive products operated from a standing position, pedals shall be placed not more than 300 mm above the surface of the floor;	☐	☐	☒	
e) for assistive products operated from a standing position, hand operated controls shall be placed at a height of 800 mm to 1 200 mm above the surface of the floor;	☐	☐	☒	
f) handles for pushing and/or pulling shall be placed at a minimum height of 900 mm.	☒	☐	☐	
24. Requirements for information supplied by the manufacturer				
24.1 General				
The information supplied by the manufacturer comprises the data in the instructions for use and the details on the label. The information applied to, and supplied with, assistive products shall conform to EN 1041. Assistive products covered by the scope of a specific standard shall also, in addition to EN 12182, conform to the requirements according to the clause dealing with information regarding electrical aspects of the product. Any means of provision of information with assistive products shall take into account the intended users, the conditions of use and any issues specific to individual assistive product types that are necessary for the safe and effective use of the product. Special attention shall be				

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
paid to the user information, particulary the instructions on operation and the design of labels and the design and presentation of warnings. Further guidance on requirements for persons with different type of impairments can be found in CEN/CENELEC guide 6:2002, tables 1, 2, 4 and 6, and in annex C, cognitive impairment. In addition, the manufacturer should provide the information in the instructions for use in three separate sections: pre-sale, user and service information as specified in 24.2.1, 24.2.2 and 24.2.3. These may be provided as separate printed documents or in other forms of media to meet the needs of individual users or their assistants. Further guidance on the preparation of instructions can be found in EN 62079. If the manufacturer is not located in the European Community, the manufacturer is required to designate an 'EC authorised representative' established in the European Community. In such cases and to comply fully with the Essential Requirements of EU Directive 93/42/EEC on medical devices, the name and address of the authorised representative are required.				
24.2 Instructions for use				
24.2.1 Pre-sale information				
In addition to the requirements of 24.1, pre-sale information shall include the following:				
a) information on how to obtain the user information in a format appropriate for use by people with visual, reading or cognitive disabilities;	☒	☐	☐	
b) all information shall as far as possible be available in Pictogram;	☒	☐	☐	
c) a description of the intended use and the intended environment;	☒	☐	☐	
d) maintenance instructions, if applicable;	☒	☐	☐	
e) if an assistive product is intended to be cleaned, a description of the method and suitable cleaning materials, including precautions needed to avoid corrosion, if applicable;	☒	☐	☐	
f) if an assistive product is intended to be disinfected, a description of the method and suitable materials, including any precautions needed to avoid corrosion, if applicable;	☒	☐	☐	
g) the overall dimensions (width, length and height) of the assistive product, expressed in millimetres, and its mass, expressed in kilograms, when it is ready for use and, if applicable, when it is folded or dismantled;	☒	☐	☐	
h) the mass expressed in kilograms if the assistive product can be dismantled or has any removable parts that has a mass which is heavier than 10 kg;	☒	☐	☐	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
i) if the assistive product is supposed to be used in combination with other products, the manufacturer shall state to which products, and how this can be done in a safe way;	☒	☐	☐	
j) warning about dangerous combinations of devices (e.g. cushions for the prevention of decubitus ulcers often only work on correct seat surface) and combinations of flame resistant and non-flame resistant material;	☒	☐	☐	
k) a list of accessories, detachable parts and materials that the manufacturer has determined as being intended for use with the assistive product;	☒	☐	☐	
l) if a programmable controller is fitted, information on the method of programming, the competence required to carry out the programming and the effects on performance;	☐	☐	☒	
m) operator control adjustments;	☐	☐	☒	
n) whether and how the assistive product can be folded or dismantled to assist in storage or transport;	☒	☐	☐	
o) instructions regarding transport of the assistive product (e.g. in a car or aeroplane);	☒	☐	☐	
p) measured sound power level.	☐	☐	☒	
24.2.2 User information				
User information shall be provided by the manufacturer with each assistive product. Information shall contain all pre-sale warnings and informations as applicable for each assistive product.	☒	☐	☐	
User information shall contain the following as applicable for each assistive product:				
a) the location and the type of identification number/word on the assistive product shall be given for the unique identification number of the assistive product;	☒	☐	☐	
b) the intended user;	☒	☐	☐	
c) any adjustment or settings required before the assistive product can be used and information on how adjustments or settings affect the assistive product;	☒	☐	☐	
d) information on adjustment possibilities and the competence required to carry out these adjustments;	☒	☐	☐	
e) instructions on operation of all controls;	☐	☐	☒	
f) the battery type and nominal voltage;	☐	☐	☒	
g) instructions for battery maintenance;	☐	☐	☒	
h) instructions for operating the battery charger, including warnings regarding any potential safety hazards (e.g. a possibility of gas accumulating in the charging area);	☐	☐	☒	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
i) instructions on dismantling and re-assembly of the assistive product or any removable parts;	☒	☐	☐	
j) the positions of points where the component parts can be gripped for safe moving and handling and/or a method for handling during dismantling, assembly or carrying;	☒	☐	☐	
k) a warning if surface temperatures can increase / decrease when exposed to external sources of heat or cold (e.g. sunlight, outdoor environment);	☒	☐	☐	
l) a warning if the assistive product might disturb the operation of devices in its environment that emit electromagnetic fields (e.g. alarm systems of shops, automatic doors, etc.);	☐	☐	☒	
m) a warning if the performance of the assistive product can be influenced by electromagnetic fields (e.g. those emitted by portable telephones, electricity generators or high power sources);	☐	☐	☒	
n) if the intended purpose of an assistive product cannot be met without a hazard (e.g. holes, V-shaped opening), a warning and instructions on how to operate the assistive product safely;	☐	☐	☒	
o) if the intended purpose of an assistive product cannot be met without a hazard due to moving parts such as squeezing, a warning and instructions on how to operate the assistive product safely;	☐	☐	☒	
p) the level of resistance to ignition of materials and assemblies;	☒	☐	☐	
q) information on the recycling of used batteries and other parts of the assistive product;	☐	☐	☒	
r) expected lifetime of the assistive product.	☒	☐	☐	
24.2.3 Service information				
The service information shall contain all the pre-sale information, user information and instructions necessary for the maintenance, adjustment and repair of the assistive product and for the replacement of parts.	☒	☐	☐	
The service information shall contain all the pre-sale information and the user information.	☒	☐	☐	
The service information shall be sufficiently detailed concerning preventive inspection, maintenance and calibration, including the frequency of such maintenance.	☒	☐	☐	
The service information shall provide information for the safe performance of such routine maintenance necessary to ensure the continued safe use of the assistive product.	☒	☐	☐	

Test methods and -requirements:	Compliance			Comments:
	Pass	No	N/A	
Additionally, the service information shall identify the parts on which preventive inspection and maintenance shall be performed by service personnel, including the periods to be applied and details about the actual performance of such maintenance.	☒	☐	☐	
24.3 Labelling				
In addition to the requirements of 24.1, the manufacturer shall apply permanent labels for the year of production for the product;	☒	☐	☐	
Detachable parts of an assistive product with a mass of more than 10 kilograms shall be marked with the actual mass on the part.	☐	☐	☒	
Symbols for use in the labelling of medical devices shall be in accordance with EN 980.	☒	☐	☐	
25. Packaging				
The hazards that can be caused by inadequate protective packaging shall be assessed in the risk analysis (see 4.1).	☒	☐	☐	

Test equipment:		Used:
PM 3081	Digitaler Messschieber 150 mm	☒
PM 1013	Rampe	☒
PM 3060	Elektronische Kranwaage	☒
PM 3114	Maßband	☒
PM 1064	ISO-Dummy / Aufnahme	☒

Photos:

Photo 1

Photo 2

Photo 3

Photo 4

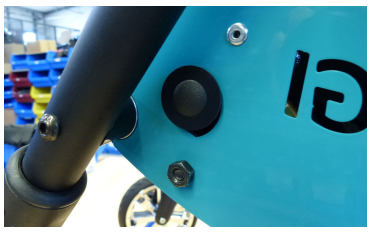


Photo 5

Photo 6

Submitted documents:	
Specification of product modifications	2015-09-21 (Änderungen BINGO Evolution.pdf → Differences between Bingo Evolution 2015 and the basic version of 2010)
Specification of product modifications	2015-10-02 (Statement of Hoggi)
Pre-sale information	2015-10-02 (Vorverkaufsinformation_BINGO_Evolution_V1.1.pdf)
User manual	2015-10-02 (Bedienungsanleitung_BINGO_Evolution_BA_D_09-2015_V1.1.pdf)
Service information	2015-09-21 (Serviceanleitung_Bingo-Evolution_SA_D_09-2015.pdf)
Risk analysis	2015-09-23 (Risikomanagementakte_BINGO_Evolution_V2_1-1.pdf
Clinical evaluation	2015-09-21 (Klinische_Bewertung_BINGO Evolution.pdf)
Biocompatibility	2015-09-21 (HygCen GmbH; SN 12252)
Biocompatibility	2015-09-21 (HygCen GmbH; SN 17325)
Flammability	2015-09-21 (Textilni Zkusebni Ustav, s.p.; No.: 13-059)
Conformation	2015-09-21 (Konformitätsbewertung BINGO Evolution.pdf)
Test report	2011-07-08 P-10-339-MP-PA041-E-N1, Berlin Cert GmbH
Test report	2011-07-08 P-10-339-MP-PA129-E-N1, Berlin Cert GmbH

Notes:
In contrast to the original version of Bingo Evolution (see submitted documents: test report P-10-339-MP-PA129-E-N1), the transportation in motor vehicles is intended for the modified version of this product. The submitted report of crash test has not been evaluated by the Berlin Cert GmbH, since the crash test was conducted by a non-accredited institute.