Test Report Number: GZHH00641706

Applicant: ZHONGSHAN QUNN MEDICAL EQUIPMENT CO., LTD
NO.108 ZHAOYI ROAD,XIAOLAN TOWN,
ZHONGSHAN CITY,GUANGDONG CHINA 528414

Date: May 26, 2026

Attn: CATHY YANG

Sample Description:

One (1) piece of submitted sample said to be :

Item Name	:	**QX06**
Item No.	:	**FD88QX6,EG-01**
Applicant Specified Age Grading for Testing	:	50-80
Manufacturer	:	Zhongshan Qunn Medical Equipment Co., Ltd
Country of Destination	:	China
Country of Origin	:	Zhongshan,China
Date Sample Received	:	Apr 14, 2026 & May 25, 2026
Testing Period	:	Apr 14, 2026 to May 26, 2026

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To be continued

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Tests conducted:

As requested by the applicant, refer to attached page(s) for details.

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Conclusion:

Tested sample	Standard	Result
Submitted sample	ISO 11199-2: 2021+ A1: 2024 – Assistive products for walking manipulated by both arms - Requirements and test methods – Part 2: Rollators Excluding: Clause 6.1: Risk analysis Clause 7: Materials Clause 8: Ingress of liquids Clause 9: Temperatures of parts that come in contact with human skin Clause 10.1: Safety of moving parts (Squeezing) Clause 11.1: Prevention of traps for parts of the human body (Holes and clearance) Clause 19: Packaging	Pass

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Authorized by:
For Intertek Testing Services Shenzhen Ltd.
Guangzhou Branch, Hardlines

Victor T.J. Wang
General Manager

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1 Requirements and test methods for Rollators

With reference to ISO 11199-2: 2021+ A1: 2024 – Assistive products for walking manipulated by both arms - Requirements and test methods – Part 2: Rollators, the submitted sample was subjected to the following tests.

Number of sample tested: One (1) piece.

Initial inspection: No visible defect was found.

Overall dimensions: 585 mm W x 750 mm D x 839~989 mm H

Weight: 9.2 kg

Executive summary:

Clause	Test Items	Verdict
1	Scope	--
2	Normative references	--
3	Terms and definitions	--
4	Apparatus	--
5	Test conditions	--
6	General requirements and test methods	--
6.1	Risk analysis The safety of a rollator shall be assessed by the manufacturer by identifying hazards and estimating the risks associated with them using the procedures specified in ISO 14971. If relevant, ISO 12100 can be used additionally. When a rollator is intended by the manufacturer to be used in combination with other devices, the risks shall be assessed by the manufacturer.	NR
6.2	Rollators that can be dismantled If it is intended that a rollator can be dismantled for storage or transportation, it shall not be possible to reassemble it in a manner that presents a hazard. Hazard condition should be checked by disassembling and reassembling the rollator according to the manufacturer's instruction. The fasteners that are loosened or removed to allow dismantling shall not be single use fasteners.	P
6.3	Fasteners All load- bearing fasteners shall be either self-locking or fitted with a locking device to prevent inadvertent detachment.	P
6.4	User mass/load limit The maximum user mass shall be specified by the manufacturer. For load carrying accessories, the load capacity of the accessories shall be specified by the manufacturer.	P (R: Maximum user mass: 136 kg Load accessories: 5 kg)

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6.5	Structure requirements A rollator shall be designed to be maneuverable for indoor use or a combination of the two: For indoor use on a level surface: - The front wheel diameter shall be greater or equal to 75mm; For outdoor use: - The front wheel diameter shall be greater or equal to 180mm; The wheel width shall be greater or equal to 22mm;	P (Indoor use & Outdoor use)
6.6	Brakes	--
6.6.1	General requirements All rollators shall have running brakes that are easy to operate by the user when the rollator is in motion. All rollators that have a resting seat shall have parking brakes that can be integrated with the running brakes. All rollators that are designed for outdoor use shall have parking brakes that can be integrated with the running brakes. Maximum grip distance for operating running brakes shall be not greater than 75mm, measured. If the effectiveness of the brake will be reduced by wear, it shall have means for the compensation of wear. Brake performance shall not be adversely affected by folding, unfolding or adjusting actions. If readjustment of the brakes is necessary following an adjustment action of the rollator, tools shall not required.	P
6.6.2	Brake effectiveness This requirement applies to both, parking brakes and running brakes. The rollator shall not have not move more than 10 mm in 1 min if the running brake or the parking brake is activated. The Maximum force to apply and release the brakes shall not exceed - 60N for pushing forces, and - 40N for pulling forces. Operating device acts on both wheels, each of the brake-operating devices shall be tested separately.	P
6.6.3	Durability of brakes This requirement applies to both parking brakes and running brakes. No part of the brakes shall crack or break and the effectiveness of the brake shall meet the requirements in 6.6.2.1 after the durability test. Test cycles: 100 000 Frequency: ＜0.5Hz	P
6.7	Handgrip The handgrip width shall be no less than 20 mm and not more than 50 mm. This shall be checked by measurement. The handgrip shall be securely fixed to the handle of the rollator.	P
7	Materials	--

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7.1	General The materials used in a rollator should not mark, or scratch. The rollator materials should not cause discoloration of skin or clothing when the rollator is in normal use. Manufacturers should, wherever possible, use materials that can be recycled for further use. It shall be stated in the instructions for use which parts can be recycled.	NR
7.2	Flammability Risk of flammability that can affect user safety shall be assessed by the manufacturer in the risk analysis. Parts identified by risk of flammability shall be tested according to ISO 8191-2. Residual risks should be reported in the instruction.	
7.3	Biocompatibility and toxicity Materials that come into contact with the human body shall be assessed for biocompatibility using the guidance in ISO 10993-1. The result of the assessment shall be incorporated in the risk analysis.	
7.4	Infection and microbiological contamination The rollator and its auxiliary parts should be designed to be accessible for cleaning to prevent cross infection.	
7.5	Resistance to corrosion The risk of corrosion affecting the safety of the user or an assistant shall be assessed in the risk analysis. Assistive products for walking that are identified to be at risk of corrosion shall be sufficiently protected against corrosion. The salt spray test according to ISO 9227 with a test duration of 72 hours can be used.	
8	Ingress of liquids If liquid can come unintentionally into any cavitied or enclosure, it shall be able to drain through drain holes again. The hazards that can be caused by the ingress of liquids shall be assessed in the risk analysis.	NR
9	Temperatures of parts that come in contact with human skin The risk analysis shall identify hazards and evaluate the risks associated with the surface temperature of parts that can come into contact with human skin during the intended conditions of use. The risk analysis shall use: a) The range of ambient temperatures to be expected during the intended use and foreseeable misuse; b) The ergonomic data on acceptable temperatures of touchable surfaces according to ISO13732-1; Use of the rollator by people with insensitive skin and/or damaged skin: the maximum temperature shall not exceed 41°C when measured according to the test methods given in ISO13732-1.	NR
10	Safety of moving parts	--

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<table>
<tr><td>10.1</td><td>Squeezing

If the intended purpose cannot be achieved without a hazard such as risk of squeezing. (e.g. the elbow or knee flexion of limb prothesis)
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 a rollator 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 1.
These measurements shall be done before and after any relevant strength, durability and impact testing.
Table 1 — Safe distances between moving parts
<table><tr><th>To avoid</th><th>Safe distances for adults</th><th>Safe distances for children [a]</th></tr><tr><td>Finger traps</td><td>Less than 8 mm or more than 25 mm</td><td>Less than 4 mm or more than 25 mm</td></tr><tr><td>Foot traps</td><td>Less than 35 mm or more than 120 mm</td><td>Less than 25 mm or more than 120 mm</td></tr><tr><td>Head traps</td><td>Less than 120 mm or more than 300 mm</td><td>Less than 60 mm or more than 300 mm</td></tr><tr><td>Genitalia traps</td><td>Less than 8 mm or more than 75 mm</td><td>Less than 8 mm or more than 75 mm</td></tr></table>[a] Also includes adults with a height of less than 146 cm, or a mass of less than 40 kg, or a BMI of less than 17.
For moving parts that can cause squeezing, manufacturers shall take into consideration what part/parts of the body are at risk. The user/user group has to be specified, so that correct safety distances can be applied.</td><td>NR</td></tr>
<tr><td>10.2</td><td>Mechanical wear

Parts subject to mechanical wear likely to result in a safety hazard shall be accessible for inspection, unless it is intended to be replaced by a service interval specified by the manufacturer.</td><td>P</td></tr>
<tr><td>11</td><td>Prevention of traps for parts of the human body</td><td>--</td></tr>
<tr><td>11.1</td><td>Holes and clearance

Holes in and clearances between stationary parts that are accessible to the user and/or assistant during the intended use of a rollator shall be as specified in Table 2.
These measurements shall be done before and after any relevant strength, durability and impact testing.
Table 2 — Safe distances between stationary parts
<table><tr><th>To avoid</th><th>Safe distances for adults</th><th>Safe distances for children [a]</th></tr><tr><td>Finger traps</td><td>Less than 8 mm or more than 25 mm</td><td>Less than 5 mm or more than 12 mm</td></tr><tr><td>Foot traps</td><td>Less than 35 mm or more than 100 mm</td><td>Less than 25 mm or more than 45 mm</td></tr><tr><td>Head traps</td><td>Less than 120 mm or more than 250 mm</td><td>Less than 60 mm or more than 250 mm</td></tr><tr><td>Genitalia traps</td><td>Less than 8 mm or more than 75 mm</td><td>Less than 8 mm or more than 75 mm</td></tr></table>[a] Also includes adults with a height of less than 146 cm, or a mass of less than 40 kg, or a BMI of less than 17.
If the intended purpose of a rollator cannot be met without a hazard by the size of holes and the clearance between stationary parts, a waring and instructions on how to operate the rollator safety shall be provided in the instructions for use.
For stationary parts that can cause a trap, manufacturers shall take into consideration what parts of the body are at a risk. A warning and instruction on how to operate the assistive product for walking safety shall be provided in the instruction for use.
The design of parts that confine a hole or clearance shall take into consideration the forces that can be applied in normal use.</td><td>NR</td></tr>
</table>

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11.2	V-shape openings On holes with the shape of a keyhole or V-shaped openings the lower limit shall not apply. When inspecting the rollator for traps for body parts, any flexibility/elasticity of adjacent parts shall be taken into account.	NA
12	Folding, adjusting and locking mechanisms	--
12.1	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 a rollator incorporates folding and/or adjusting mechanisms, it shall conform to clause 10 and 11. If the rollator is height adjustable, the increments shall not exceed 25mm/ Adjustments shall be securely fixed when in use. The maximum allowable elongation shall be clearly marked. After the durability test, the adjustment/folding mechanisms shall operate as intended by the manufacturer.	P
12.2	Folding mechanisms To avoid a hazard where parts of the body can be trapped when the rollator is folded, the following shall be assessed: - The rollator shall incorporate means to protect the user from trapping and/or squeezing hazards; or - The gap between exposed parts of a rollator 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 1; or - If the intended purpose of a rollator cannot be met without a hazard such as squeezing, a warning and instruction on how to operate the rollator safely shall be provided in the instructions for use. If guards are applied, the design of a guard shall take into consideration the forces that can be applied in normal use.	P
12.3	Locking mechanisms Locking mechanisms shall be required to maintain the rollator in the folder or in the working configuration if the absence of the locking device presents a hazard to the user. Locking mechanisms shall lock securely and shall be protected from unintended release.	P
13	Carrying handles	--
13.1	General Manufacturers should note that national or other requirements can demand mass limits in excess of the following. If a rollator or a part of a rollator has a mass of 10 kg or more and the intended purpose is for it to be portable or to be handled according to manufacturer's instruction, it shall either a) Have one or more handles suitably placed that enable the rollator or part to be carried by two or more persons, or be provided with suitable handing devices, or The instructions for use shall indicate the points where the rollator or its part can be lifted safely and describe how they should be handled during lifting, assembly and/or carrying.	NA

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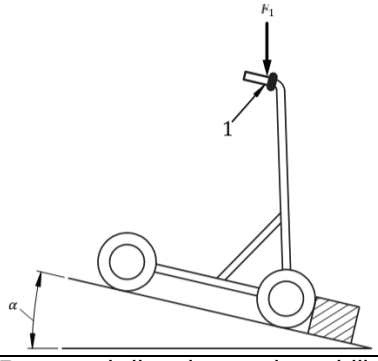
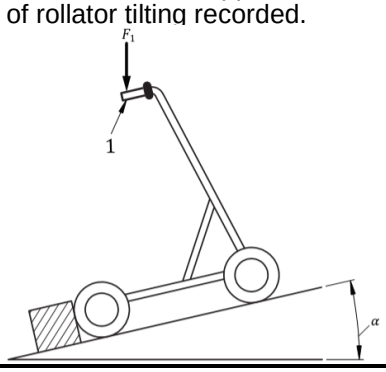
13.2	Requirements If a rollator incorporates carrying handles or grip, they shall not become detached from the rollator and there shall not be any permanent distortion, cracking or other evidence of failure when tested as specified in 13.3. After the completion of the test the rollator shall operate as intended by the manufacturer.	NA
14	Surfaces, corners and edges If not required for the intended function for a rollator, all accessible edges, corners and surfaces shall be smooth and be free from burrs and protruding parts and sharp edges shall be rounded or chamfered. If not required for the intended function, the rollator shall not have protruding parts. Where possible, necessary protruding parts shall have protection to prevent injury and/or damage.	P
15	Static stability	--
15.1	Requirements for static stability The rollator shall not tilt when tested according to 15.2. In forward/backward/sideways direction, the angle of the plane at the point of rollator tilting shall be not less than 15.0°/7°/3.5° from the horizontal.	P
15.2.1	Forward-direction static stability test The rollator shall be placed with its wheels on a test plane. The loading force of 250N shall be applied vertically to the rollator. The test plane at the point of rollator tilting recorded.  	P (Tilting angle: 22.4°)
15.2.2	Rearward-direction static stability test The rollator shall be placed with its wheels on a test plane. The loading force of 250N shall be applied vertically to the rollator. The test plane at the point of rollator tilting recorded.  	P (Tilting angle: 14.2°)

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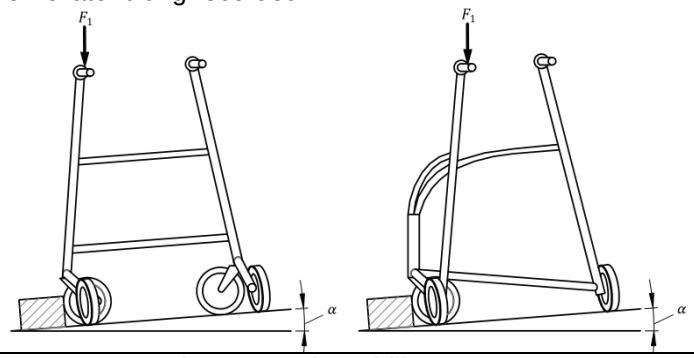
15.2.3	Sideway-direction static stability test The rollator shall be placed with its wheels on a test plane. The loading force of 250N shall be applied vertically to the rollator. The test plane at the point of rollator tilting recorded.  	P (Tilting angle: Left: 4.40° Right: 3.70°)
15.2.4	Accessory equipment static stability test Rollators being supplied with accessories such as a drip holder, basket, tray, shopping bag and/or oxygen cylinder holder shall be tested for static stability in accordance with 15.2.1, 15.2.2 and 15.2.3, depending on where on the rollator the accessories are fixed. During the tests, the drip holder shall be loaded to maximum capacity, the basket, tray or shopping bag shall be loaded to the capacity specified by the manufacturer and the oxygen cylinder shall be full.	P (Tilting angle: Forward-direction: 20.8° Rearward-direction: 18.5° Sideway-direction: Left: 6.50° Right: 5.70°)
16	Static strength	--
16.1	Static strength of resting seat	--
16.1.1	General The rollator shall be tested in the most adverse condition as described in clause 5.	P
16.1.2	Requirements for static strength of resting seat No part of the rollator shall crack or break. Vertical loading: 1632N User mass: 136kg	P
16.2	Static strength of rollator	--
16.2.1	General The rollator shall be tested in the most adverse condition as described in clause 5.	P

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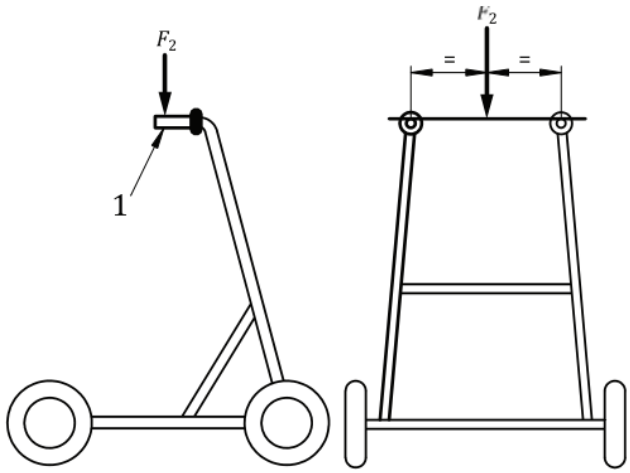
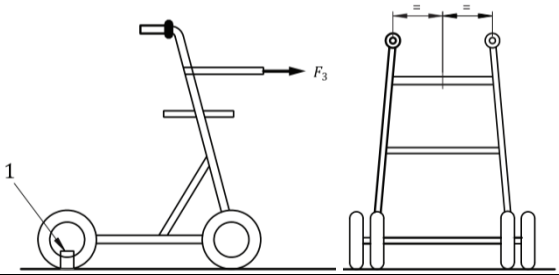
16.2.2	Requirements for static strength of rollator No part of the rollator shall crack or break and the permanent set of the rollator height shall not exceed 1%. Vertical loading: 1632N User mass: 136kg Maintained time: 1 min. 	P
16.3	Strength of backrest	--
16.3.1	The rollator shall be tested in the most adverse condition as described in clause 5.	P
16.3.2	Requirements for strength of backrest No part of the rollator shall crack or break. Test load: 612N User mass: 136 kg Test time: 10 Maintained time: 1 min. 	P
17	Durability test The rollator shall be tested in the least stable position as described in clause 5.	P

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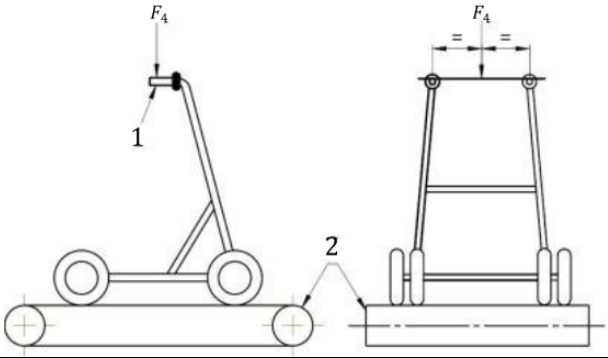
17.1	Requirement for durability No part of the rollator shall crack or break and all adjustments and locking devices shall work as intended.	P

Vertical loading	1088N
User mass	136 kg
Test time	200000
Speed	＞0.4m/loading cycle
Frequency of the cyclic loading	1Hz



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<tr><td>18</td><td>Ergonomic principles

An assistive product for walking shall be designed to the ergonomic principles set out in EN614-1+A1, taking into account the special needs of the person with a disability for whom the assistive product is intended. Grips, handles and pedals shall suit the functional anatomy of the user, according to the intended use and meet with the following requirements:
a) The distance between any handle (part intended to be grabbed) requiring an operating force of more than 10N and any construction part of the assistive product shall not less than 35mm;
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 75mm;
c) The diameter of any operating handles and/or knobs requiring an operating force of more than 10N shall be between 19mm and 43mm;
d) For assistive products operated from a standing position, pedals (tipping aid) shall be placed not more than 300mm above the surface of the floor;
e) For assistive products operated from a standing position, hand operated controls shall placed at a height of 800mm to 1200mm above the surface of the floor;
f) For a rollator operated from a sitting position, controls intended to be opened by the occupant while seated shall be within the occupant's reach space;
g) The operating forces or torques required for those parts of the rollator that are designed to be operated by fingers, hands/arms or feet shall not exceed the values in Table 3.
Table 3 — Operating forces
<table><tr><th>Operation</th><th>Force/torque</th></tr><tr><td>operation by using a finger</td><td>5 N</td></tr><tr><td>operation by using a hand/arm (pushing)</td><td>60 N</td></tr><tr><td>operation by using a hand/arm (pulling)</td><td>40 N</td></tr><tr><td>operation by using a foot</td><td>300 N</td></tr><tr><td>operation by turning</td><td>1,9 Nm</td></tr><tr><td>rotation of seat surface</td><td>60 N</td></tr></table></td><td>P</td></tr>
<tr><td>19</td><td>Packaging

The hazards that can be caused by inadequate protective packaging shall be assessed in the risk analysis.</td><td>NR</td></tr>
<tr><td>20</td><td>Information supplied by the manufacturer</td><td>--</td></tr>
</table>

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20.2	Information marked on the product Each rollator shall be clearly and indelibly marked with the following: a) manufacturer's model identification name and / or number; b) whether or not the rollator is designed for indoor or outdoor use; c) maximum user mass; d) name or trade name and address of the manufacturer or authorized representative according to local requirements; e) year and month of manufacture; f) maximum safe working load (to be marked on the accessories) g) maximum width of the rollator; h) maximum allowed angle between the longitudinal centre line of the handle and the direction of motion, if the handles are sideways adjustable; all information shall as far as possible be available in Pictogram in accordance with ISO7000 and ISO15223-1	P
20.3	Instruction manual Instruction manual shall contain the followings for the rollator: a) information on how to obtain the user information in a format appropriate for use by people with visual, reading or cognitive disabilities; b) a description of the intended use including intended user and the intended environment; c) maximum user mass; d) maximum safe working load for load carrying accessories such as basket, tray, shopping bag, etc.; e) minimum and maximum height of the rollator; f) maintenance instructions, if applicable; g) if the rollator is intended to be cleaned, a description of the method and suitable cleaning materials, including precautions needed to avoid corrosion, if applicable; h) if the rollator is intended to be disinfected, a description of the method and suitable materials, including any precautions needed to avoid corrosion, if applicable; i) the overall dimensions (width, length and height) of the rollator, expressed in millimeters, and its mass, expressed in kilograms, when it is ready for use and, if applicable, when it is folded or dismantled; j) the mass expressed in kilograms, if the rollator can be dismantled or has any removable parts that has a mass that is heavier than 10 kilograms; k) if the rollator is supposed to be used in combination with other products, the manufacturer shall state which products, and how this can be done in a safe way; l) a list of accessories, detachable parts and materials that the manufacturer has determined as being intended for use with the rollator; m) whether and how the rollator can be folded or dismantled to assist in storage or transport;	P (Soft copy)

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Test Report Number: GZHH00641706

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Clause	Test Items	Verdict
	n) the location and the type of identification number/wood on the rollator shall be given for the unique identification number of the assistive product; o) any adjustment or settings required before the rollator can be used and information on how adjustments or setting affect the rollator; p) information on adjustment possibilities and the competence required to carry out these adjustments; q) instructions on operation of all controls; r) instructions on dismantling and re-assembly of the rollator or any removable parts; s) the positions of points where the component parts can be gripped for safe moving and handling and/or a method for handing during dismantling, assembly or carrying; t) a warning if surface temperatures can increase/decrease when exposed to external sources of heat (e.g. sunlight, outdoor environment); u) if the intended purpose of the rollator cannot be met without a hazard, a warning and instructions on how to operate the assistive product safety; v) if the intended purpose of the rollator cannot be met without a hazard due to moving parts such as squeezing, a warning and instructions on how to operate the rollator safely; w) how to obtain information about the warranty; x) warning of the risk of falling from the rollator such as “Incorrect use can lead to hazardous situation – Do not use the products to transport a person”.	

Abbreviation: P = Pass; NA = Not Applicable; NR = Not Required by client

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End of report

*The statements of conformity reported have considered the decision rule agreed, namely that Intertek have taken account of measurement uncertainty as calculated by Intertek, and applied according to ILAC-G8/09:2019 (Non-binary acceptance based on guard band **w** = **U**) except designation from the customer, regulation or test specification. This decision rule only applies to the numeric test results.*

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