

Test report No.: P - 10-243 - MP - PA 025 - E - N1

Walking aids manipulated by both arms (Rollators) / English Version

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Test institute: Berlin Cert - Prüf- und Zertifizierstelle für Medizinprodukte GmbH
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Client: Trust AB, Vikingaplan 1, S-21618 Malmö

Manufacturer: Trust AB, Vikingaplan 1, S-21618 Malmö

Test sample: Type / model: Rollator, user weight 130 kg
Quantity / Identification: 1 / Nameplate was filed later
Receipt / condition: 2010-08 / new



Test standard: DIN EN ISO 11199-2:2005 Walking aids manipulated by both arms - Requirements and test methods - Part 2: Rollators

Annotation: The numbering corresponds to the applied standard
DIN EN ISO 11199-2:2005

**Code according to
DIN EN ISO 9999: 2007:** 12 06 06 Rollators (Devices with handgrips and two or more wheels, possibly in combination with tips; included are rollators with a seat for resting)

Accreditation: Accredited by the "Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten" ZLG-P-946.97.02

Kind of the test: Complete test


Test period: 2010-09-21 to 2011-05-27

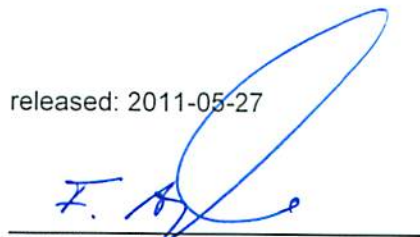
Test location: Rooms of the test institute

Test result: The test requirements are fulfilled.

established: 2011-05-27

released: 2011-05-27


Dipl.-Ing. M. Fiedler


Dipl.-Ing. F. Aßmann

This test report may only be quoted in full. Any use for advertising purpose must be granted in writing.

This report is the result of a single examination of the object in question and is not generally applicable evaluation of the other products in regular production.



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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 Requirements				
4.1 Manoeuvrability				see Testreport P-10-194-MP-PA025-E
The wheel diameter shall be not less than 75 mm.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	measured: 243 mm
The wheel diameter of rollators manufactured for outdoor use shall be not less than 180 mm.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
The wheel width of rollators manufactured for outdoor use shall be not less than 22 mm.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	measured: 33 mm
4.2 Stability				
Forward stability $\geq 15,0^\circ$	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	measured: $> 15,2^\circ$
Backward stability $\geq 7,0^\circ$	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	measured: $7,1^\circ$
Sideways stability $\geq 3,5^\circ$	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	measured: left $> 3,5^\circ$ right $> 3,8^\circ$
4.3 Brakes				
All rollators with more than two wheels shall have running brakes that are easy to operate by the user when the rollator is in motion.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
All rollators with more than two wheels and which have a resting seat, or are designed for outdoor use, shall have parking brakes, which may be integrated with the running brakes.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Maximum grip distance for operating running brakes shall be no greater than 75 mm.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
If the effectiveness of the brake will be reduced by wear, it shall have means for the compensation of wear.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Brake performance shall not be adversely affected by folding, unfolding or adjusting actions. If re-adjustment of the brakes is necessary following an adjusting action of the rollator, tools shall not be required (e.g. height adjustment).	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Test of running brakes				
The rollator shall not move more than 10 mm in 1 min. on an inclined plane of 6° .	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Load F = 650 N
Test of parking brakes				
Maximum force to apply and release parking brakes shall not exceed:				
a) 60 N (pushing force);	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b) 40 N (pulling force).	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
The rollator shall not move more than 10 mm in	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Load, F = 650 N

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Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
1 min. on an inclined plane of 6°.				
4.4 Handgrip				see Testreport P-10-194-MP-PA025-E
The handgrip width shall be no less than 20 mm and not more than 50 mm.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	This requirement is not applicable to anatomic handgrips. Measured: 20 mm
The handgrip shall be securely fixed to the handle of the rollator as judged by the inspector.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
The handgrip shall be replaceable or easy to clean.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.5 Legsection and tip				see Testreport P-10-194-MP-PA025-E
Where there is no wheel, the leg section shall end in a tip designed to prevent the leg section from piercing through it, when the rollator is used as intended by the manufacturer.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Where there is no wheel, the tip shall be replaceable.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Where there is no wheel, the tip shall not cause discolouring of the walking surface, as verified by visual inspection.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Visual inspection
That part of the tip that contacts the walking surface shall have a minimum diameter of 35 mm. Compliance shall be verified by measurement.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
The rubber tip shall be securely fixed to the leg of the rollator as judged by the inspector.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
4.6 Resting seat				see Testreport P10 -194-MP-PA025-E
When tested in accordance with the static loading test no part of the rollator shall crack or break.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Load F = 1530 N
4.7 Mechanical durability				see Testreport P10 -194-MP-PA025-E
When tested in accordance with the static loading test no part of the rollator shall crack or break and the permanent set of the rollator height shall not exceed 1%.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Load F = 1530 N Height before performing: 94,1 mm Height after performing: 93,7 mm Height reduction: 0,4 %
When tested in accordance with the fatigue test, no part of the rollator shall crack or break.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Load F = 1020 N; f = 1Hz; LW = 200.000
4.8 Adjusting devices				
Each of the height adjustment devices shall be clearly marked with its maximum allowable elongation.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
After the fatigue test, the adjustment / folding mechanisms shall operate as intended by the	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
manufacturer.				

Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
4.9 Folding mechanism				see Testreport P-10-194-MP-PA025-E
When the walking aid is in the working position, the folding mechanism shall stay securely locked, as judged by the inspector.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4.10 Adjustment of handles				see Testreport P-10-194-MP-PA025-E
The handles may be adjustable but shall be securely fixed when in use and verified by inspection.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
On rollators having handles that may be angled or positioned so that they come outside the rollator and jeopardizes the stability of the rollator, either a physical stop shall prevent the unsafe position or a warning showing the safe limits of adjustment shall be fixed on the rollator. The instructions for use shall explain the consequences such an adjustment may have on the stability.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
4.11 Materials and finish				see Testreport P10 -194-MP-PA025-E
The rollator materials shall not cause discolouring of skin or clothing when the rollator is in normal use.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Visual inspection
All parts of the rollator shall be free from burrs, sharp edges or projections that could cause damage to clothing or discomfort to the user.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6 Information supplied by the manufacturer				
6.1 General				
The information applied to, and supplied with, rollators shall conform to the relevant parts of EN 1041 together with, but not limited to, the following requirements.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
The information shall include advice on which other devices and/or types of devices that can be used in combination with the rollator in question, and any precautions or limitations needed to ensure user safety.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.2 Information marked on the product and/or accessories				
Each rollator shall be clearly and indelibly marked:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
a) maximum user mass;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b) maximum safe working load (SWL) to be marked on accessories;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c) maximum allowed angle between the longitudinal centreline of the handle and the direction of motion, if	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	

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Test methods and -requirements:	Compliance:			Comments:
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the handles are sideways adjustable;				
d) manufacturer's name or trade name and address;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e) manufacturer's model identification name and/or number;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
f) month and year of manufacture;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
g) maximum extension of the height adjustment, marked on the adjusting members;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
h) maximum width of the rollator;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
whether or not the walking aid is designed for indoor or outdoor use.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.3 Documentation				
The following information shall be contained in the instructions for use and / or assembly, or clearly and indelibly marked on the product:				
a) maximum rollator height;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b) minimum rollator height;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
c) maintenance and cleaning instructions, including a description of the method and suitable cleaning agents and any precautions needed to avoid corrosion and/or ageing of the materials used in construction of the rollator;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d) instructions for assembly, adjustment of all kinds, folding and unfolding;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e) warnings and advice about precautions relating to safe distances between moving and stationary parts;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
f) maximum safe working load (SWL) for load carrying accessories such as basket, tray, shopping bag, etc.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Technical data:	
Max. body weight of the user:	130 kg
Idle weight / with accessories:	6,4 kg / no accessories
Tyres:	f 243 / b 197 mm
Distance between mid-lines of handgrips:	460 mm
Overall dimensions (l x w x h):	650 / 600 / 960 mm
Folded dimensions (l x w x h):	650 / 600 / 960 mm
Brake system:	2 x radial on the wheels operated pushing brake, adjustable
Max. turning width:	760 mm
Angle between the longitudinal centreline of the handle and the direction of motion:	0°

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Submitted documents:	
User manual	Stand: 2011-05
Biocompatibility	Testreportnr.: GZ1102013877/CHEM, SGS, 2011-02-23
Flammability test	Testreportnr.: GZHGR2009020758, SGS, 2008-08-05

Test equipment:		used
PM 3081	Digitaler Messschieber 150mm	<input checked="" type="checkbox"/>
PM 3082	Digitaler Messschieber 150mm	<input type="checkbox"/>
PM 3034	Neigungsmesser - digital	<input checked="" type="checkbox"/>
PM 1012	Kipp-Plattform	<input checked="" type="checkbox"/>
PM 3060	Elektronische Kranwaage	<input checked="" type="checkbox"/>
PM 1025	Maßband	<input checked="" type="checkbox"/>
PM 1046	Hydraulikprüfstand (Käfig)	<input checked="" type="checkbox"/>
PM 3045	elektronisches Handkraftmessgerät	<input checked="" type="checkbox"/>
PM 1054	Exzenterprüfstand 1	<input checked="" type="checkbox"/>
PM 1055	Exzenterprüfstand 2	<input type="checkbox"/>

Notes: