

# Test report No.: P - 08 - 015 - MP - PA 021 - E

Shower and toilet chair, toilet stool, shower bench, mobile shower couch and accessories / English Version

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**Test institute:** Berlin Cert - Prüf- und Zertifizierstelle für Medizinprodukte GmbH  
an der Technischen Universität Berlin  
Dovestr. 6, D-10587 Berlin  
Tel.: +49(0)30-314-25111, Fax: -23719

**Client:** Mobilex A/S, Nørskovvej 1, DK-8660 Skanderborg

**Manufacturer:** Mobilex A/S, Nørskovvej 1, DK-8660 Skanderborg

**Test sample:** Type / model: Swivel bather / 302022  
Quantity / Identification: 1 / no labelling on the product  
Receipt / condition: 2008-01-14 / new



Handed in later

**Basis of tests:** The tests are performed according to internal standards of the Berlin Cert GmbH according to:  
ISO 7176-1:1999 Wheelchairs - Part 1: Determination of static stability  
ISO 7176-8:1998 Wheelchairs - Part 8: Static, impact and fatigue strength  
ISO 7173:1989 Furniture - Chairs and stools - Determination of strength and durability  
DIN EN 60601-2-38:2001 Medical electrical equipment - Part 2-38: Particular requirements for the safety of electrically operated hospital beds

**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:** 2008-01-15 to 2008-02-26


**Test location:** Rooms of the test institute

**Test result:** The test requirements are fulfilled.

established: 2008-02-26

released: 2008-02-26

  
\_\_\_\_\_  
Dipl.-Ing. M. Kyslenko

  
\_\_\_\_\_  
Dipl.-Ing. T. Knitter

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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																	
<b>1. General requirements</b>																				
Requirements according DIN EN 12182	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	See test report no.: P-08-015-MP-PA041-E, Berlin Cert GmbH																
Limits of max. adjustment ranges for e.g. armrests and footrests have to be marked	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																	
<b>2. Test of static stability</b>																				
Requirement: Tilting angle $\geq 2^\circ$ in all directions	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<table border="1"> <thead> <tr> <th colspan="4">Stability</th> </tr> <tr> <th></th> <th>for-wards</th> <th>side-wards</th> <th>back-wards</th> </tr> </thead> <tbody> <tr> <td>Seat position</td> <td>°</td> <td>°</td> <td>°</td> </tr> <tr> <td>Leaned forward</td> <td>°</td> <td>°</td> <td>°</td> </tr> </tbody> </table>	Stability					for-wards	side-wards	back-wards	Seat position	°	°	°	Leaned forward	°	°	°
Stability																				
	for-wards	side-wards	back-wards																	
Seat position	°	°	°																	
Leaned forward	°	°	°																	
<b>3. Static strength</b>																				
<p>A test sample shall meet all the following requirements at the conclusion of the tests:</p> <ul style="list-style-type: none"> <li>- No component shall be fractured or have visible cracks.</li> <li>- No nut, bolt screw, locking-pin, adjustable component or similar item shall have become detached after having been tightened, adjusted or refitted once.</li> <li>- No electrical connector shall be displaced or disconnected.</li> <li>- All parts intended to be removable, foldable or adjustable shall operate as described by the manufacturer.</li> <li>- All power-operated systems shall operate as described by the manufacturer.</li> <li>- Handgrips shall not be displaced.</li> <li>- Any multiposition or adjustable component shall not be displaced from the preset position.</li> <li>- No component or assembly of parts shall exhibit deformation, free play or loss of adjustment that adversely affects the function of the test sample.</li> </ul>																				
Static strength of seat acc. to DIN EN 12182	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Load: F = 1950 N																
Static strength of armrest acc. to ISO 7176-8	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Load: F = 990 N (downward)																
Static strength of table top	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Load: F = N																

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Test methods and -requirements:	Compliance:			Comments:
	Pass	No	N/A	
Static strength of backrest acc. to ISO 7173	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Load: Fstat = 560 N, Fbal = 1300 N
Static strength of footrests acc. to ISO 7176-8	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Load: F = N
Leg forward static load acc. to ISO 7173	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Load: Fstat = ___ N, Fbal = ___ N, by F = ___ N tilting
Leg sideways static load acc. to ISO 7173	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Load: Fstat = ___ N, Fbal = ___ N, by F = ___ N tilting
<b>4. Dynamic strength</b>				
<p>A test sample shall meet all the following requirements at the conclusion of the tests:</p> <ul style="list-style-type: none"> <li>- No component shall be fractured or have visible cracks.</li> <li>- No nut, bolt screw, locking-pin, adjustable component or similar item shall have become detached after having been tightened, adjusted or refitted once.</li> <li>- No electrical connector shall be displaced or disconnected.</li> <li>- All parts intended to be removable, foldable or adjustable shall operate as described by the manufacturer.</li> <li>- All power-operated systems shall operate as described by the manufacturer.</li> <li>- Handgrips shall not be displaced.</li> <li>- Any multiposition or adjustable component shall not be displaced from the preset position.</li> <li>- No component or assembly of parts shall exhibit deformation, free play or loss of adjustment that adversely affects the function of the test sample.</li> </ul>				
Dynamic strength of seat	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Load: F = 900 - 1700 N, load-cycle changes: 100000
Dynamic strength of armrest	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Load: F = 260 - 650 N, load-cycle changes: 20000
Dynamic strength of table top	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Load: F = - N, load-cycle changes: 20000
Dynamic strength of backrest acc. to ISO 7173	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Load: F = 330 N (up to 200 kg UW), load-cycle changes: _____
Drop Test acc. to ISO 7173	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Drop height: 450 mm, load-cycle changes: 10

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Test methods and -requirements:	Compliance:			Comments:
	pass	no	N/A	
<b>5. Requirements for mobile shower couch (acc. to EN 60601-2-38 clause 21)</b>				
Side rails:				
- have to be equipped with the possibility to be locked or engaged in upright / closed position	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
- accidentally disengagement or unlocking in normal use does not appear.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
- side rails are not in upright/locked position if not locked or engaged	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Additional requirements for shower couch which is intended to be mobile while accommodating a patient				
Impact test:				
- without permanent deformation or loss of normal use	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Static strength of side rail	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Static stability of shower couch	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Static strength of head and foot panel assemblies	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Threshold test:				
- without permanent deformation or loss of normal use	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
<b>6. Information supplied by the manufacturer</b>				
<b>6.1 Labeling and Information marked on the product</b>				
- each product shall be clearly and indelibly marked with the following:	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- maximum permissible user mass;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- manufacturer's name or trade name and address;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- manufacturer's model identification name and/or number.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>6.2 Instructions for use include:</b>				
- technical data;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- manufacturer's name or trade name and address;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- intended purpose;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- maximum permissible user mass;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- overall view;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- information about operating;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- information about tools for reparation and/or for adjustment of parts;	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
- register of accessories;	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
- annotation about used symbols and pictograms on the product;	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
- safety instructions	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- defined information for mounting at the wall (method of mounting);	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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

Test methods and -requirements:	Compliance:			Comments:
	pass	no	N/A	
- recommended methods of cleaning and care;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- information about warranty;	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
- warning notice for dangerous adjustments.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Technical data:	
Max. body weight of the user:	130 kg
Overall weight:	4,6 kg
Tip Ø:	n.a.
Overall dimensions (l x w x h):	520 mm / 700 mm / 540 mm
Backrest angle to seat surface:	95°
Seat surface height at front edge:	200 mm
Seat width / - length:	410 mm / 330 mm
Fixation on WC:	n. a.
Fixation at the wall:	n. a.
Fixation on the bath tube with setting range (for bath tube interior area):	hang up

<b>Submitted documents:</b>	see test report no.: P-08-015-MP-PA041-E
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Test equipment:		used
PM 3031	Digitaler Messschieber (180 mm)	<input checked="" type="checkbox"/>
PM 3034	Neigungsmesser - digital	<input checked="" type="checkbox"/>
PM 1012	Kippplattform	<input type="checkbox"/>
PM 3060	Elektronische Kranwaage	<input checked="" type="checkbox"/>
PM 1025	Maßband (7,5 m)	<input checked="" type="checkbox"/>
PM 1046	Hydraulikprüfstand (Käfig)	<input checked="" type="checkbox"/>
PM 3024	Kraftmessdose	<input checked="" type="checkbox"/>
PM 3045	Elektronisches Handkraftmessgerät	<input checked="" type="checkbox"/>

<b>Notes:</b>