



CENTRE FOR TESTING AND CERTIFICATION - MECH-TEST
Mechanical Laboratory

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Date 8.05.2015

TEST REPORT NO. *CBC-044/2015*

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Subject of testing: *Shower chair with tilt – wide model* **Classification according to PN-EN ISO 9999:2011:**
09 33 03

Type / Model: -- **Factory ref.no.:** *302025*

Manufacturer: *MOBILEX A/S* **Number of specimens:** *1*
Grønlandsvej 5, DK-8660 Skanderborg

Applicant: *A-Net s.c.*
93-469 Łódź, ul. Łaskowice174

Kind of testing *Testing scope according to application of Client*
Mechanical testing for conformity with
PN-EN 12182:2012, PN-EN 12183:2010 cl.7.3, 7.4.1, 7.5, 7.8, 7.10,
ISO 7176-1:1999, ISO 7176-3:2003, PN-ISO 7176-8:2002 cl. 10.4.2,
PN-EN 1021:2007

Test started: *23.04.2015*

Test finished: *8.05.2015*

Approved by:

DYREKTOR

mgr inż. Andrzej Tkaczyk

Special comments / enclosures:

1) *Annex 1,2 – Identification of wheelchair elements*

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Test results refer only to tested units.

Test results reported here are not applicable to the further modifications of the product affecting its structure, material or technology.

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PHOTO OF WHEELCHAIR



MOBILEX A/S
Grønlandsvej 5
DK - 8660 Skanderborg
Tel: +45 87 93 22 20
www.mobilex.dk

Shower chair
with tilt



Max. 130 kg



Produced

Serial no.

TESTING

NORMATIVE REFERENCES

	Applied
PN-EN 12182:2012 Technical aids for disabled persons – General requirements and test methods	YES
PN-EN 12183:2011 Manually propelled wheelchairs – Requirements and test methods	YES
PN-EN 12184:2010 Electrically powered wheelchairs, scooters and their chargers – Requirements and test method	NO
ISO 7176-1:1999 Wheelchairs – Determination of static stability	YES
ISO 7176-2:2001 Wheelchairs – Determination of dynamic stability of electric wheelchairs	NO
ISO 7176-3:2003 Wheelchairs – Determination of efficiency of brakes	YES
ISO 7176-4:2008 Wheelchairs – Energy consumption of electric wheelchairs and scooters and determination of theoretical distance	NO
ISO 7176-5:2008 Wheelchairs – Determination of overall dimensions, mass and turning space	NO
ISO 7176-6:2001 Wheelchairs – Determination of maximum speed, acceleration and retardation of electric wheelchairs	NO
PN-ISO 7176-7:2001 Wheelchairs – Measurement of seating and wheel dimensions	NO
PN-ISO 7176-8:2002 Wheelchairs – Requirements and test methods for static, impact and fatigue strengths	YES
ISO 7176-9:2009 Wheelchairs – Climatic test for electric wheelchairs	NO
ISO 7176-10:2008 Wheelchairs – Determination of obstacle-climbing ability of electric wheelchairs	NO
PN-ISO 7176-14:2001 Wheelchairs – Power and control systems for electric wheelchairs – Requirements and test methods	NO (Electrotechnical Laboratory)
PN-ISO 7176-15: 2002 Wheelchairs – Requirements for informative disclosure, documentation and labelling	NO
PN-EN 1021-1:2007 Furniture. Assessment of ignitability of upholstered furniture. Ignition source: smouldering cigarette.	YES
PN-ISO 7176-16:2001 equivalent: PN-90/P-04823 Wheelchairs. Resistance to ignition of upholstered parts – Requirements and test methods	NO
PN-ISO 7176-19:2007 Wheelchairs. Wheeled mobility devices for use in motor vehicles	NO

TEST RESULTS according to PN-EN 12182 : 2012

Requirements according to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Test result	Opinion	Comments
4.1	4.8, 5.2, 5.4.2, 5.5, 6, 8.2.1, 9.4, 10, 22, 24 i EN 1441	Risk analysis	--	N/T	
4.2	V/I	Expected characteristics and technical documentation	Conf.	Pos.	
4.3	EN ISO 14155	Clinic assessment	--	N/T	
4.4	V/I	Technical support which can be dismantled	Conf.	Pos.	
4.5	V/I	Single use connections	Conf.	Pos.	
4.6	V/I	Boundary values of user weight	Conf.	Pos.	
4.7	V/I	Immobilising means	Conf.	Pos.	
4.8	V/I, C5	Suitability of the product for people with cognitive impairment	--	N/T	
		The presence of the description in the manufacturer's documentation	--	N/T	
Materials					
5.1	EN 60601-1-9	Recycling	--	N/T	
5.2	V/I, B 5.2	Flammability	Conf.	Pos.	NOTE 10
5.2.2	V/I	Upholstered parts, mattresses, bed bases and bedding	--	N/A	
5.2.3	V/I, EN 1021	Upholstered parts	--	N/A	
5.2.4	V/I, EN 597	Mattresses and bed bases	--	N/A	
5.2.5	V/I, EN ISO 12952	Bedding	--	N/A	

Requirements according to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Test result	Opinion	Comments	
5.2.6	V/I. EN 60695-11-10	Moulded parts	--	N/T		
5.3	EN ISO 10993-1 Annex. D	Biological conformity and toxicity	--	N/T		
5.4	V/I	Contaminants and residues	--	N/A		
5.5	V/I.,B.5.5.1	Microbiological infections and contamination	Cleaning	Conf.	Pos.	Comments in service manual
	V/I.,B.5.5.1		Disinfection	--	N/A	
	V/I., EN ISO 22442-1 B.5.5.2		Animal tissue	--	N/A	
5.6	EN ISO 9227	Resistance to corrosion	--	N/T		
6		Emitted sound and vibration				
6.1	EN ISO 3746 B6	Noise and vibration	--	N/A		
6.2	EN ISO 3746	Sound levels and frequencies of audible warning devices	--	N/A		
6.3	EN ISO 3746	Feedback	--	N/A		
7	EN 60601-1-2 7.2, 7.3, 7.4	Electromagnetic compatibility	--	N/A		
8		Electrical safety	--	N/A		
9	V/I	Overflow, spillage, leakage, and ingress of liquids	--	N/A		
10	V/I. Measur.	Surface temperature	--	N/A	$t^{\circ} \leq 41^{\circ}C$ ■ requirement does not concern heat of direct solar radiation - PN-EN 12182, clause 10a ■ requirement concerns only persons with insensitiveness of skin (who do not feel heat) - PN-EN 12182, clause 10d	
11	V/I	Sterility	--	N/A		
12	V/I. Measur.	Safety of moving parts	Conf.	Pos.	Note in service manual	
13	V/I. Measur.	Prevention of traps for parts of the human body	Conf.	Pos.	Note in service manual	
14	V/I	Folding and adjusting mechanisms	Conf.	Pos.	Note in service manual	
15	V/I. Measur.	Carrying handles	Conf.	Pos.	Note in service manual	
16	V/I. Measur.	Assistive products which support or suspend users	Conf.	Pos.	NOTE 6	
17	V/I. Measur.	Portable and mobile assistive products	Conf.	Pos.	NOTE 7	
18	V/I, B 18	Surfaces, corners, edges and protruding parts	Conf.	Pos.		
19	B 19	Hand held assistive products	--	N/A		
20	B 20	Small Parts	Conf.	Pos.	NOTE 8	
21	V/I. Measur. EN 60601-1	Stability	Conf.	Pos.	NOTE 9	
22	B 22, V/I	Forces in soft tissues of the human body	Conf.	Pos.		
23	V/I. EN 614-1	Ergonomic principles	Conf.	Pos.		

Requirements according to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Test result	Opinion	Comments
24	V/I	Requirements for information supplied by the manufacturer			
24.1		General	--	N/T	
24.2		Instructions for use	--	N/T	
24.2.1	V/I	Pre-sale Information			
		a) information on how to obtain the user information in a format appropriate for use by people with visual, reading or cognitive disabilities	--	N/T	
		b) all information shall as far as possible be available in Pictogram	--	N/T	
		c) a description of the intended use and the intended environment;	--	N/T	
		d) maintenance instructions, if applicable;	--	N/T	
		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;	--	N/T	
		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;	--	N/T	
		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	--	N/T	
24.2.1	V/I	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;	--	N/T	
		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;	--	N/T	
		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;	--	N/T	
		k) a list of accessories, detachable parts and materials that the manufacturer has determined as being intended for use with the assistive product	--	N/T	
		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	--	N/T	
		m) operator control adjustments	--	N/T	
		n) whether and how the assistive product can be folded or dismantled to assist in storage or transport	--	N/T	
		o) instructions regarding transport of the assistive product (e.g. in a car or aeroplane)	--	N/T	
		p) measured sound power level	--	N/T	
24.2.2	V/I	User information			
		User information shall be provided by the manufacturer with each assistive product. Information shall contain all pre-sale warnings and informations and the following as applicable for each assistive product:	--	N/T	
		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	--	N/T	
		b) the intended user	--	N/T	
		c) any adjustment or settings required before the assistive product can be used and information on how adjustments or settings affect the assistive product	--	N/T	
		d) information on adjustment possibilities and the competence required to carry out these adjustments	--	N/T	
		e) instructions on operation of all controls	--	N/T	
		f) the battery type and nominal voltage	--	N/T	
		g) instructions for battery maintenance	--	N/T	
		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);	--	N/T	

Requirements according to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Test result	Opinion	Comments
24.2.2.2	V/I	i) instructions on dismantling and re-assembly of the assistive product or any removable parts;	--	N/T	
		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;	--	N/T	
		k) a warning if surface temperatures can increase / decrease when exposed to external sources of heat or cold (e.g. sunlight, outdoor environment);	--	N/T	
		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.);	--	N/T	
		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/T	
		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;	--	N/T	
		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;	--	N/T	
		p) the level of resistance to ignition of materials and assemblies;	--	N/T	
24.2.2	V/I	q) information on the recycling of used batteries and other parts of the assistive product;	--	N/T	
		r) expected lifetime of the assistive product.	--	N/T	
		- It is recommended to include instructions on how to solve simple problems for the ease of use.	--	N/T	
24.2.3	V/I	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.	--	N/T	
		The service information shall contain all the pre-sale information and the user information.	--	N/T	
		The service information shall be sufficiently detailed concerning preventive inspection, maintenance and calibration, including the frequency of such maintenance.	--	N/T	
		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.	--	N/T	
		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.	--	N/T	
24.3	V/I	Labelling	--	N/T	
		- year of production for the product	--	N/T	
		- Detachable parts of an assistive product with a mass of more than 10 kilograms shall be marked with the actual mass on the part.	--	N/T	
		- Symbols for use in the labelling of medical devices shall be in accordance with EN 980	--	N/T	
25	V/I	Packaging	--	N/T	

Pos. – positive; Neg – negative; N/T – not tested; N/A – not applicable; N/R – not required, N/O – not occurred, V/I.- visual inspection, Conf.- conformed.

NOTE 1: Service manual not evaluated

NOTE 2: During visual inspection before testing any visible defects that can have an effect on test results were not stated.

NOTE 3: Sample/object for testing was delivered to the Laboratory by the Orderer.

NOTE 4: Test dummy of mass 150 kg were used for testing.

NOTE 5: Environment temperature for testing - 19°C, humidity of air 60%.

- NOTE 6:
- *Wheelchair was loaded with a static load of 1,5 times the mass of the user for a period of time 70 seconds. A positive test result.*
 - *The test was conducted of the wheelchair loaded with the mass of the user on fatigue two-drum test stand according to PN ISO 7176-8:2002, clause 10.4.2. After 200 000 cycles, the wheelchair worked in accordance with the manufacturer's information (obstacles removed).*
 - *The fatigue tests of parking brakes was conducted according to PN EN 12183: 2010, clause 7.4.1. After 60 000 cycles of turning on and off, the brakes are operated in accordance with the manufacturer's information. After the endurance test, the effectiveness of the parking brakes was tested according to ISO 7176-3.*

No turning or slip of wheels when setting the wheelchair on the ramp with a slope of 7°.

Prior to the fatigue testing, the switching power was measured, the parking foot brake release, in accordance with section B23. The strength of turning on was 60 N, the strength of the release was - 30 N.

- NOTE 7:
- *There were made three dumps of the wheelchair with a full load of 30mm. A positive test result.*
 - *Three-time raiding of the wheelchair with a full load at a speed of 0.4 m / s on the step of height 8mm. The test positive.*
 - *Three-time raiding of the wheelchair with a full load at a speed of 0.4 m / s from the step of height 40mm. The test positive.*
 - *Three times hitting the vertical wooden barrier by the front of the wheelchair with a full load, running at a speed of 0.4 m / s. Positive test result.*

In connection with the possibility of rollover of the wheelchair with a full load on the step of max. 8 mm in height, there is a note in the manual on using the wheelchair on a horizontal surface, free of steps / obstacles.

- NOTE 8: *This manual includes a note on the protection of the product against access by children under 5 years due to the possibility of small parts that could fit without the use of force in the sampler small parts, which could be swallowed by small children.*

- NOTE 9: *The stability was tested according to ISO 7176-1:1999.*

Rear stability is: 11,0 °,

Front stability is: 8,2 °,

Lateral stability is 12,0 °.

- NOTE 10: *Flammability of upholstery and filling material was tested in accordance with PN-EN 1021-1:2007 (method of smoldering cigarette). During the test of the upholstered panels and foam materials there was no progressive smoldering and progressive burning.*

There is no ignition of upholstery fabric surface.

CONCLUSIONS:

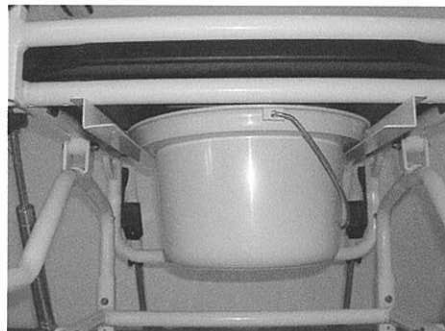
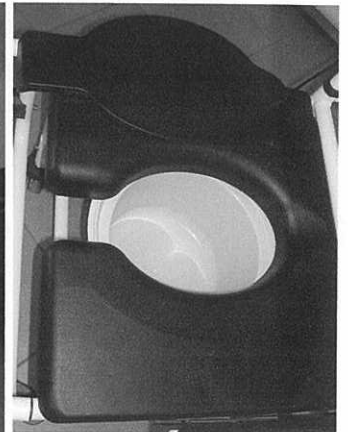
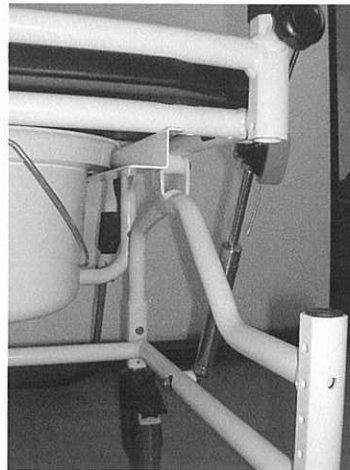
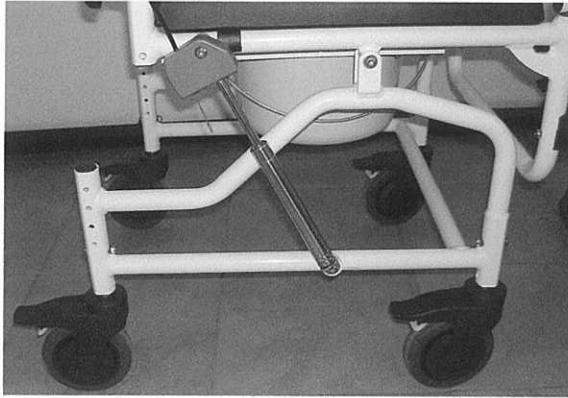
*Testing object **conforming** with requirements of PN-EN 12182:2012*

Note: Conformity assessment of product according to standard requirements refer to the scope of mechanical tests ordered by client, excluding testing of material biocompatibility with human body according to PN-EN ISO 10993-1:2010

- END -

ANNEX 1 TO TEST REPORT No. CBC-044/2015

Identification of wheelchair elements



ANNEX 2 TO TEST REPORT No. CBC-044/2015

Identification of wheelchair elements

