

# RE FOR TESTING AND CERTIFICATION - MECH-TEST

## **Mechanical Laboratory**

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Date 4.12.2019

## TEST REPORT NO. *CBC-143/2019*

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Subject of testing:

Shower chair

Classification according to

PN-EN ISO 9999:2017-02: 09 12 03

Type / Model:

"Kakadu" shower chair

SN .: --

Item no.: 3020U8 HMI-nr.: 62314

Number of specimens: 1

Manufacturer:

MOBILEX A/S.

Grønlandsvei 5

DK-8660 Skanderborg

Applicant:

A-Net s.c.

93-469 Łódź, ul. Łaskowice 174

Kind of testing

Testing scope according to application of Client

Mechanical testing for conformity with

PN-EN 12182:2012, PN-EN 12183:2014 cl. 7.2.1, 9.2, 9.2.1.e, 7.1.1, 8.5.

ISO 7176-1:2014,ISO 7176-3:2012. PN-ISO 7176-8:2014 cl. 10.3.2.

PN-EN 1021-1:2007

Test started: 31.10.2019

Test finished: 4.12.2019

Approved by:

inż. Andrzej Tkaczyk

Special comments / enclosures:

1) Annex 1,2 - Identyfication of product 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. This test report shall be neither copied differently as in the whole nor be published without written consent of the Laboratory.



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## CHARACTERISTIC OF MANUALLY PROPELLED WHEELCHAIR

		Item no.: 3020U8	
Maximum loa	d capacity: 150 kg	Overall mass of wheelchair: 12,1	5 kg
	Description		Comments
Dimensions:	Length:	970 mm	
	Height:	964 - 1038 mm	
	Width:	562 mm	
	Height of armrests of the seat:	202 mm	
	Height of seat (min/max):	488 - 563 mm	
	Width x length of seat:	450 x 420 mm	
	Distance between armrests:	460 mm	
	Clearance of footrest:	5 - 175 mm	
	Angle of armrests:	-0,5°	
	Angle of seat plane:	0,00	
	Angle of footrest:	12,40	
Construction	Material:	Aluminum	
of frame:	Method of fastening frame elements:	Welding, rivets, bolts	
	Folding/unfolding:	Unfolding	
Castor wheels	Ø of wheel:	99 mm	<del>-  </del>
(front):	Width:	29 mm	
().	Material of ring of a wheel:	Plastic	
	Material of fork:	Plastic	
	Vertical adjustment (number of fixing positions):		
	Horizontal adjustment (number of fixing positions).		
	Adjustment of axis inclination angle:	NO NO	
Rear wheels:	Ø of wheel:	99 mm	
icai wiiceis,	Width:	29 mm	
	Material of ring of a wheel:	Plastic	
	Vertical adjustment (number of fixing positions):		
Backrest	Folding/unfolding:	Unfolding	
Dacki est	Backrest inclination stepless:	NO	
	adjustment stepless.		
Tilt levers	Two singular:	NO	
THE ICVELS	One lateral:	NO	
Push handles	Kind:	One transverse	
Parking brake	Left:	YES	
	Right:	YES	
	Kind:	4 x foot	
	Material of lever:	Plastic	
	Fastening to frame:		
	Way of adjustment:		
Upholstery	Material:	Plastic	
	Colour:	black	
Legrests	Common for both legs:	NO	
	Separate for each leg:	YES	
	Stationary:	NO	
	Folding:	YES	
	Vertical adjustment (number of fixing positions)	YES stepless	
	Horizontal adjustment (number of fixing position	s): NO	
	Angle adjustment (number of fixing positions):	NO	
	Material of legrest:	Aluminum, plastic	
Accessories	Seat belt	NO	
	Anti-overturn device:	NO	
	Anterior pelvic support:	NO	
	Service :	YES	STATUTE AND CO.

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## PHOTO OF WHEELCHAIR





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**TESTING** 

		IESTING			
		NORMATIVE REFERENCES			Applied
PN-EN 12182:2012 Technical aids for disabled persons – General requirements and test methods					YES
PN-EN 12183:2014 Manually propelled wheelchairs – Requirements and test methods					YES
method		trically powered wheelchairs, scooters and their chargers -	Requirements an	d test	NO
ISO 7176-1:2014 Wheelchairs – Determination of static stability					
		hairs - Determination of dynamic stability of electric when	elchairs		NO
		hairs – Determination of efficiency of brakes			YES
	7 <b>6-4:2008</b> Wheelc cal distance	hairs - Energy consumption of electric wheelchairs and sc	ooters and determ	nination of	NO
		hairs – Determination of overall dimensions, mass and turn	ning space		NO
SO 717		hairs - Determination of maximum speed, acceleration and	d retardation of el	ectric	NO
		eelchairs - Measurement of seating and wheel dimensions			NO
PN-ISO	7176-8:2014 Wh	eelchairs - Requirements and test methods for static, impa	ct and fatigue stre	engths	YES
SO 717	76-9:2009 Wheelc	hairs - Climatic test for electric wheelchairs			NO
SO 717	76-10:2008 Wheel	chairs – Determination of obstacle-climbing ability of elec	tric wheelchairs	1) 80 10 100 100	NO
PN-ISO	7176-14:2001 W	heelchairs – Power and control systems for electric wheelch	hairs – Requirem	ents and	NO
est metl	hods	*			(Electrotechnica Laboratory)
PN-ISO	7176-15: 2002 W	/heelchairs - Requirements for informative disclosure, doc	cumentation and la	abelling	NO
PN-EN igarette		iture. Assessment of ignitability o upholstered furniture. Iş	gnition source: sm	nouldering	YES
PN-ISO		uivalent: PN-90/P-04823 Wheelchairs. Resistance to ignit	ion of upholstered	l parts –	NO
		chairs. Resistance to ignition of upholstered parts – Requir	ements and test n	nethods	NO
		heelchairs. Wheeled mobility devices for use in motor veh			NO
		TEST RESULTS according to PN-EN		12	
Kequirement s 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.	
4.0	V/I, C5	Suitability of the product for people with cognitive impairment		N/T	
4.8		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	
E 2 2	V/I, EN 1021	Upholstered parts		N/A	
5.2.3	V/I, EN 597	Mattresses and bed bases		N/A	
5.2.3 5.2.4	V/1, EN 59/				
	V/I, EN 39/ V/I. EN ISO 12952	Bedding		N/A	- N

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Requirement s according to clause	Test method according to clause	charact	Checked characteristics/assemblies/parameters		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		
	V/I.,B.5.5.1	Rg Cleaning		Conf.	Pos.	Comments in service manual	
	V/I.,B.5.5.1	Microbiologica I infections and contamination	Disinfection		N/A		
5.5	V/L, EN ISO 22442-1 B.5.5.2		Animal tissue		N/A		
5.6	EN ISO 9227	Resistance to o	orrosion		N/T		
6		Emitted sound	d and vibration				
6.1	EN ISO 3746 B6	Noise and vibr	ation		N/A		
6.2	EN ISO 3746	Sound levels a	nd frequencies of audible warning devices		N/A		
6.3	EN ISO 3746	Feeedback			N/A		
7	EN 60601-1-2 7.2, 7.3, 7.4	Electromagnetic compatibility			N/A		
8	102, 110, 111	Electrical safety			N/A		
9	V/I	Overflow, spill	age, leakage, and ingress of liquids		N/A		
10	V/I. Measur.	Surface temper	ature		N/A	t <sup>0</sup> ≤ 41°C  ■ requirement does not concern heat of direct solar radiation - PN EN 12182,clause 10a  ■ requirement concerns only persons with insensitiveness of ski (who do not feel heat) - PN-EN 12182,clause 10d	
11	V/I	Sterility			N/A		
12	V/I. Measur.	Safety of movi		Conf.	Pos.	Note in service manual	
13	V/I. Measur.		raps for parts of the human body	Conf.	Pos.	Note in service manual	
14	V/I		justing mechanisms	Conf.	Pos.	Note in service manual	
15	V/I. Measur.	Carrying handl	1	Conf.	Pos.	Note in service manual	
16	V/I. Measur.		ects 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		rs, edges and protruding parts	Conf.	Pos.		
19	B 19	Hand held assistive products			N/A		
20	B 20	Small Parts			Pos.	NOTE 8	
21	V/I. Measur. EN 60601-1	Stability			Pos.	NOTE 9	
22	B 22, V/I	Forces in soft t	ssues of the human body	Conf.	Pos.		
23	V/I. EN 614-1	Ergonomic prir	ciples	Conf.	Pos.		



clause	Test			CBC-143/2019 Page: 6 of 8			
	method according to clause	Checked characteristics/assemblies/parameters	Test resul t	Opinion	Comme nts		
24	V/I	Requirements for information supplied by the manufacturer					
24.1		General		N/T			
24.2		Instructions for use		N/T			
	V/I	Pre-sale Information		11/ 2			
24.2.1		a) information on how to obtain the user information in a format appropriate for use by people with visual, reading orcognitive 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			
1		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			
		<li>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;</li>		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			
		<ul> <li>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;</li> </ul>		N/T			
		<ul> <li>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;</li> </ul>		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			
		<ol> <li>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</li> </ol>		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		13/ 4			
24.2.2	<b>V/1</b>	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			
		<ul> <li>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</li> </ul>		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			
		<ul> <li>d) information on adjustment possibilities and the competence required to carry out these adjustments</li> </ul>		N/T			
		e) instructions on operation of all controls		N/T			
		f) the battery type and nominal vottage		N/T			
		g) instructions for battery maintenance		N/T			
		<ul> <li>instructions for operating the battery charger, including warnings regarding any potential safety hazards (e.g. a possibility of gas accumulating in the charging area);</li> </ul>		N/T			

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Require ments accordin g to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Test resul t	Opinion	Commo
2.4.2.2	V/I	<ul> <li>i) instructions on dismantting and re-assembly of the assistive product or any removable parts;</li> </ul>		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	
		1) 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 howto operatethe assistive product safely;		N/T	1
		<ul> <li>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;</li> </ul>		N/T	
		p) the level of resistance to ignition of materials and assemblies;		N/T	
24.2.2	V/I	<ul> <li>q) information on the recycling of used batteries and other parts of the assistive product;</li> </ul>		N/T	
		r) expected lifetime of the assistive product.		N/T	
		- It is recommended to include instructions on how to sotve 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	
		Additionalty, 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	
25		- Detachabfe 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	
	V/I	- Symbole for use in the labelling of medical devices shall be in accordance with EN 980 Packaging		N/T	
Pos no	V/I			N/T	

Pos. - positive; Neg - negative; N/T - not tested; N/A - not applicable; N/R - not required , N/O - not occurred , V/L- 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 20°C, humidity of air 60%.



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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 7176-8:2014, clause 10.3.2. (look ISO 7176-8:2014, cl. 10.5). After 200 000 cycles, the wheelchair worked in accordance with the manufacturer's information (for wheels castors obstacles were removed).
- The fatigue tests of parking brakes (hand and foot brakes) was conducted according to PN EN 12183: 2014, clause 9.2.1.e.

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  $7^{\circ}$ . 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 30 N, the strength of the release was -15 N - (footbrake).

- NOTE 7: There were made three dumps of the wheelchair with a full load of 30mm. A positive test result.
  - ullet Three-time raiding of the wheelchair with a full load at a speed of 0.4 m/s on the step of height 5mm. 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. 5 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 7176-1:2014.

Rear stability is:  $-15,0^{\circ}$ ,

Front stability is: -  $14.0^{\circ}$ 

Lateral stability is:  $-12.0^{\circ}$ .

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





# **CENTRE FOR TESTING AND CERTIFICATION - MECH-TEST**

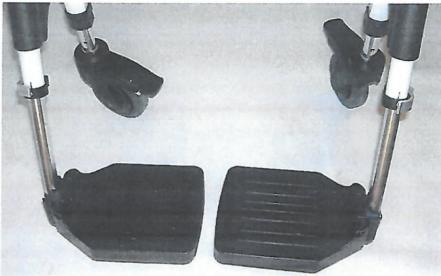
## **Mechanical Laboratory**

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#### ANNEX 1 TO TEST REPORT No. CBC-143/2019

Identification of wheelchair elements

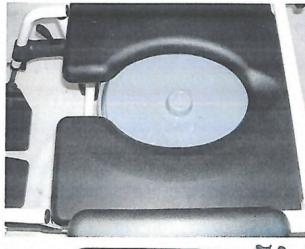


















# **CENTRE FOR TESTING AND CERTIFICATION - MECH-TEST**

## **Mechanical Laboratory**

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#### ANNEX 2 TO TEST REPORT No. CBC-143/2019

Identification of wheelchair elements



