CENTRE FOR TESTING AND CERTIFICATION - MECH-TEST
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Date 10.11.2021

TEST REPORT NO. *CBC-225/2021*

Subject of testing:	*Self standing support rail*	**Classification according to PN-EN ISO 9999:2017-02 :** *12 06 03*
Type / Model:	*Self standing support rail*	**Art.-Nr.:** *302090*
Manufacturer:	*MOBILEX A/S* *Grønlandsvej 5* *DK – 8660 Skanderborg*	**Number of specimens:** *1*
Applicant:	*A-Net s.c.* *93-469 Łódź,* *ul. Łaskowice174*	
Kind of testing	*Testing scope according to application of Client* *Mechanical testing according to PN-EN 12182:2012;*	
Test started:	*30.09.2021*	
Test finished:	*10.11.2021*	

Approved by:

DYREKTOR

mgr inż. Andrzej Tkaczyk

Special comments / enclosures:

CHARACTERISTIC OF PRODUCT

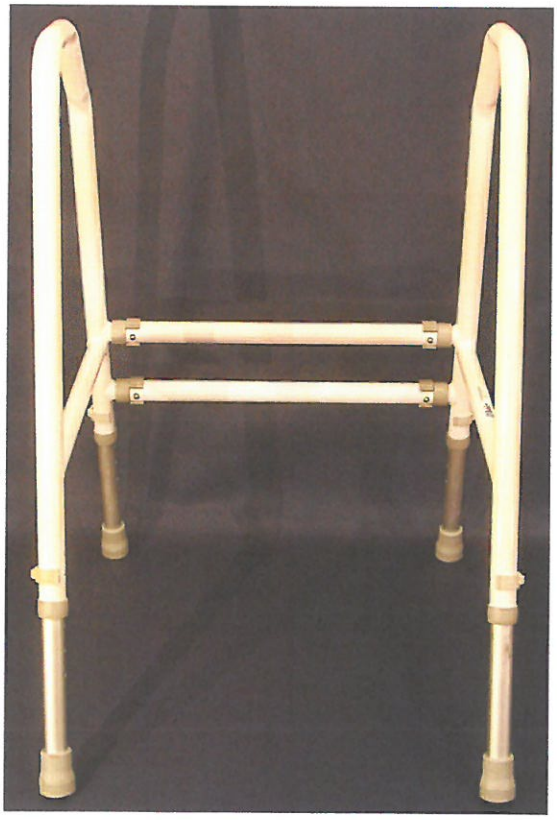
Name : *Self standing support rail* **Item no:** *302090*

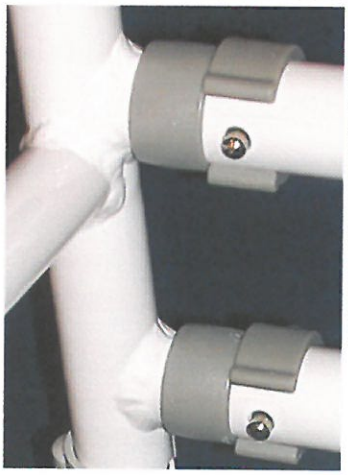
Maximum permissible user mass: *150 kg* **Mass of rollator:** *1,88 kg*

Description

Elements/parameters/materials/dimensions			Comments
Dimensions of product (fig. 3 PN-EN ISO 11199-1)	Distance between handgrips (dimension 1)	*440 mm*	
	Angle between of handgrip axis and direction of movement	*0,0°*	
	Height of product (dimension 2)	*616 mm* *786 mm*	*min.* *max.*
	Width of product (dimension 3)	*468/493/ 518 mm*	
	Turning width (dimension 4)	*695 - 790 mm*	
	Length of product (dimension 4)	*532 mm* *615 mm*	*min.* *max.*
Dimensions of folded rollator (mm)		*N/D*	
Fig. 3	Handgrip - diameter	*26 mm*	
	Handgrip - length	*90 mm*	
Tip	Diameter	*35 mm*	
	Material	*rubber*	
	Colour	*gray*	
Material of product(fig 1)	Front legs (nr. 2)	*steel*	
	Connecting elements (no. 3)		
	Rear legs (nr. 6)		
	Height adjusting device (no 7)		
	Handgrip (no 4),	*steel*	

PHOTO OF PRODUCT





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	--	*N/A*	
4.5	V/I	Single use connections	--	*N/A*	
4.6	V/I	Boundary values of user weight	*Conf.*	*Pos.*	
4.7	V/I	Immobilising means	--	*N/A*	
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	--	*N/A*	
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*	
5.2.6	V/I. EN 60695-11-10	Moulded parts	--	*N/A*	
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	--	*N/T*	
	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*	*NOTE 1*
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*	

Requirements according to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Real value	Test result	Comments
6.3	EN ISO 3746	Feeedback	--	*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*	$t^0 \leq 41^0C$ ■ *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*	

Requirements according to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Real value	Test result	Comments
12	V/I. Measur.	Safety of moving parts	--	*N/T*	
13	V/I. Measur.	Prevention of traps for parts of the human body	--	*N/T*	
14	V/I	Folding and adjusting mechanisms	--	*N/T*	
15	V/I. Measur.	Carrying handles	--	*N/T*	
16	V/I. Measur.	Assistive products which support or suspend users	*Conf.*	*Pos.*	*NOTE 2*
17	V/I. Measur.	Portable and mobile assistive products	--	*N/A*	
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.*	
21	V/I. Measur. EN 60601-1	Stability	--	*N/A*	
22	B 22, V/I	Forces in soft tissues of the human body	--	*N/A*	
23	V/I. EN 614-1	Ergonomic principles	--	*N/T*	*The requirements relate to the design process*

Requirements according to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Real value	Test result	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,r eading 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*	
		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 removab!e 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*	

Requirements according to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Real value	Test result	Comments
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 nominał vottage	--	*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 gaś accumulating in the charging area);	--	*N/T*	
		i) instructions on dismantting 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 howto operatethe 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 sgueezing, 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 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*	

Requirements according to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Real value	Test result	Comments
24.3	**V/I**	**Labelling**	--	*N/T*	
		- year of production for the product	--	*N/T*	
		- Detachabfe parts of an assistive product with a mass of morę than 10 kilograms shall be marked with the actual mass on the part.	--	*N/T*	
		- Symbole for use in the labelling of medical devices shall be in accordance with EN 980	--	*N/T*	
25	**V/I**	Packaging	--	*N/T*	*Note 3*

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: The risk of corrosion that affects the safety of the users should be evaluated in the risk analysis.

NOTE2: ●The product loaded statically with load 1.5 x maximum load (150 kg)= 225 kg for a period of time 70 sec
Test result: Positive.

NOTE 3: Assessment of package , clause 25 concerns risk of threats caused by improper protection against damage, fall or impurity during storage and transport to place of use

NOTE 4: Conformity assessment of product according to standard requirements refer to the scope of mechanical tests ordered by client

NOTE 5 : During visual inspection before testing any visible defects that can have an effect on test results were not stated.

NOTE 6: Sample/object for testing was delivered to the Laboratory by the Orderer.

CONCLUSIONS:

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

- END –