

CENTRE FOR TESTING AND CERTIFICATION - MECH-TEST

Mechanical Laboratory

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Date 9.03.2021

TEST REPORT NO. CBC-031/2021

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Number of specimens: 2

Subject of testing:

Transferboard

Classification according to

PN-EN ISO 9999:2017-02: 12 30 03

Type / Model:

Transfer board Polypropylen

Factory ref.no.: 240501

240502

Manufacturer:

MOBILEX A/S.

Polypropylen

Grønlandsvei 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

Test started: 3.03.2021

Test finished: 9.03.2021

Approved by:

REKTOR Kacry . mgr inż. Andrzej Tkaczyk

Special comments / enclosures:

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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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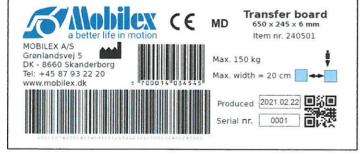
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CHARACTERISTIC OF PRODUCT

Name of product: Transfer board Maximum load capacity: 150 kg 150 kg		Factory ref.no.: 240501 240502 Overall mass of product: 0,780 kg 0,975 kg					
Dimensions:	Length:	650,0 mm	800,0 mm				
	Width:	245,0 mm	245,0 mm				
	Thickness:	6,0 mm	6,0 mm				
Material:		Polypropylen	Polypropylen				

PHOTO OF PRODUCT









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TESTING

NORMATIVE REFERENCES	Applied
PN-EN 12182:2012 Technical aids for disabled persons – General requirements and test methods	YES

TEST RESULTS according to PN-EN 12182: 2012 Requirement s according to clause Opinion Test method Test Comments Checked result characteristics/assemblies/parameters 4.8, 5.2, 5.4.2, Risk analysis 5.5, 6, 8.2.1, 9.4, 4.1 N/T10, 22, 24 i EN 1441 Expected characteristics and technical documentation Conf. Pos. 4.2 **EN ISO 14155** Clinic assessment N/T4.3 V/I Technical support which can be dismantled N/A 4.4 V/I Single use connections 4.5 N/A V/I Boundary values of user weight Pos. 4.6 Conf. V/I Immobilising means 4.7 N/AV/I, C5 Suitability of the product for people with cognitive N/Timpairment 4.8 The presence of the description in the manufacturer's N/Tdocumentation Materials EN 60601-1-9 Recycling 5.1 N/T V/I, B 5.2 Flammability 5.2 Pos. Conf. V/I Upholstered parts, mattresses, bed bases and bedding 5.2.2 N/A V/I, EN 1021 Upholstered parts 5.2.3 N/AV/I, EN 597 Mattresses and bed bases 5.2.4 N/A V/I. Bedding **EN ISO 12952** 5.2.5 N/A V/I. Moulded parts 5.2.6 N/A EN 60695-11-10 EN ISO 10993-1 Biological conformity and toxicity N/T5.3 Annex. D V/I Contaminants and residues 5.4 N/A V/I.,B.5.5.1 Microbiologica I infections and contamination Cleaning Comments in service manual Conf. Pos. V/I.,B.5.5.1 Disinfection N/A 5.5 V/L, EN ISO Animal tissue 22442-1 N/AB.5.5.2 **EN ISO 9227** Resistance to corrosion 5.6 N/T**Emitted sound and vibration** 6 **EN ISO 3746** Noise and vibration 6.1 N/AR6 **EN ISO 3746** Sound levels and frequencies of audible warning 6.2 N/A devices **EN ISO 3746** Feeedback 6.3 N/AEN 60601-1-2 Electromagnetic compatibility 7 N/A 7.2, 7.3, 7.4 8 Electrical safety N/A 9 V/I Overflow, spillage, leakage, and ingress of liquids N/A



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Requirement s according to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Test result	Opinion	Comments	
10	V/I. Measur.	Surface temperature		N/A	f' ≤ 41°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.		
13	V/I. Measur.	Prevention of traps for parts of the human body	Conf.	Pos.		
14	V/I	Folding and adjusting mechanisms	Conf.	Pos.		
15	V/I. Measur.	Carrying handles		N/A		
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		N/A		
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.		

Require ments accordin g to clause	Test 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	
24.2.1	V/I	Pre-sale Information			
24.2.1		 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	
		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	
		 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	



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Require ments accordin g to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Test resul t	Opinion	Comme nts
		 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 vottage g) instructions for battery maintenance		N/T	
		 g) instructions for battery maintenance 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 N/T	
2.4.2.2	V/I	 i) instructions on dismantting and re-assembly of the assistive product or any removable parts; 		N/T	
		 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	
		 a warning if surface temperatures can increase / decrease when exposed to external sources of heat or cold (e.g. sunlight, outdoor environment); 		N/T	3 - 40
		 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	
-		 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 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	



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Require ments accordin g to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Test resul t	Opinion	Comme nts	
24.2.3	V/I	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		
		- 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		
		- Symbole 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 (and load 9 x 25 kg).
- NOTE 5: Environment temperature for testing 20°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.
- NOTE 7: There were made three dumps of the product with a full load of 50mm (tab. 5). A positive test result.
- NOTE 8: No elements appear which would fall into the small parts cylinder.

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

