



CENTRE FOR TESTING AND CERTIFICATION - MECH-TEST

Mechanical Laboratory

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Date 29.12.2021

TEST REPORT NO. **CBC-263/2021**

Page 1 of 8

Subject of testing: *Bed lever*

Classification according to
PN-EN ISO 9999:2017-02 : 18 18 06

Type / Model: *Bed lever*

REF.: 311815

Manufacturer: *MOBILEX A/S
Grønlandsvej 5
DK – 8660 Skanderborg*

SN.: --

Number of specimens: 1

Applicant: *A-Net s.c.
93-469 Łódź,
ul. Łaskowice 174*

Kind of testing *Testing scope according to application of Client
Mechanical testing according to PN-EN 12182:2012;
EN 581-2:2015; EN 1022:2005, PN-EN 60601-2-52:2010*

Date received: 15.12.2021

Test started: 15.12.2021

Test finished: 29.12.2021

Approved by:

DYREKTOR

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.

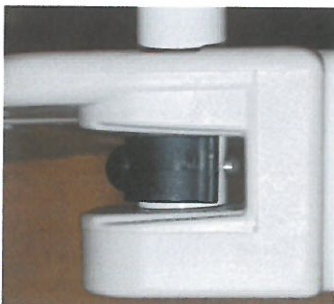
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CHARACTERISTIC OF PRODUCT

Name of product: <i>Bed lever</i>	REF.: 311815
Mass of product: 3,3 kg	Height of product: 547 mm
Maximum load: 100 kg	Length of product: 625 mm
Maximum permissible user mass: 150 kg	Width of product: 335 mm

PHOTO OF PRODUCT



		Bed lever REF 311815	
MOBILEX A/S Grønlandsvej 5 DK - 8660 Skanderborg Tel: +45 87 93 22 20 www.mobilex.dk			≤150 kg ≤100 kg
	2021.12.06 SN 0001	CE MD	

TESTING

NORMATIVE REFERENCES

	Applied
PN-EN 12182:2012 Technical aids for disabled persons – General requirements and test methods	YES
EN 581-1:2006 Outdoor furniture. Seating and tables for camping, domestic and contract use. Part 1: General safety requirements.	NO
EN 581-2:2015 Outdoor furniture. Seating and tables for camping, domestic and contract use. Part 2: Mechanical safety requirements and test methods for seating.	YES
EN 581-3:2007 Outdoor furniture. Seating and tables for camping, domestic and contract use. Part 3: Mechanical safety requirements and test methods for tables.	NO
EN 1022:2005 Domestic furniture. Seating. Determination of stability.	YES
EN 1728:2012 Domestic furniture. Seating. Test methods for the determination of strength and durability.	YES
EN 1730:2002 Domestic furniture. Seating. Test methods for the determination of strength, durability and stability.	NO
PN-EN 60601-2-52:2010 (EN 60601-2-52:2010) Medical electrical equipment – Part 2-52: Particular requirements for basic safety and essential performance of medical beds.	YES

REMARK: During the visual inspection performed before testing, no manifest defects which may affect test results were detected

TESTS OF SEATINGS

RESULT OF MECHANICAL TESTS ACCORDING TO EN 581-2:2015

Requirements according to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Real value	Test result	Comments
7.2	EN 1728 cl. 6.4	Seat static load and back static load test	--	N/A	Seat: 1600/750N - 10x10s(±2s)+ 1x 30min(±10s); Backrest: 410N 10x10s(±2s)+ 1x 30min(±10s)
7.2	EN 1728 cl. 6.5	Seat front edge static load test	--	N/A	Seat: 1300/750N - 10x 10s(±2s) + 1x 30min(±10s)
7.2	EN 1728 cl. 6.17	Combined seat and back durability test	--	N/A	25 000 cycles - Seat: 1000/750N, Backrest: 100Nm → (333N)
7.2	EN 1728 cl. 6.19	Durability test on seating with a multi-position back rest	--	N/A	only seats with adjustable rest
7.2	EN 1728 cl. 6.11	Arm rest static load test	Conf.	Pos.	vertical force 700 N
7.2	EN 1728 cl. 6.20	Arm rest durability test	Conf.	Pos.	10 000 x 400 N
7.2	EN 1728 cl. 6.15	Leg forward static load test	--	N/A	Seat: vertical force - 75kg, horizontal force 300N
7.2	EN 1728 cl. 6.16	Leg sideways static load test	--	N/A	Seat: vertical force - 1000N, horizontal force 300N x 10
7.2	EN 1728 cl. 6.24	Seat impact test	--	N/A	drop height - 180mm - 10 cycles (load 250N)
7.2	EN 1728 cl. 6.8	Foot rest static test	--	N/A	10 x 1000N
EN 1022 cl. 6.1	EN 1022 cl. 6.2	Forward stability (all seatings)	--	N/A	vertical force - 600N, horizontal force 20N, 5s
EN 1022 cl. 6.1	EN 1022 cl. 6.3	Forward stability (seatings with footrest)	--	N/A	
EN 1022 cl. 6.1	EN 1022 cl. 6.6	Rearward stability (all seatings with back)	--	N/A	Seat: vertical force - 600N, Backrest: horizontal force 109N,
EN 1022 cl. 6.1	EN 1022 cl. 6.4	Sideways stability (all seatings without arm rest)	--	N/A	vertical force - 600N, horizontal force 20N, 5s
EN 1022 cl. 6.1	EN 1022 cl. 6.5	Sideways stability (all seatings with arm rest)	--	N/A	Horizontal force: armrest - 20N Vertical force: seat - 250N, armrest - 350N
EN 1022 cl. 7.1	EN 1022 cl. 7.3	Stability of seatings which have variable geometry (canting seats)	--	N/A	
EN 1022 cl. 7.1	EN 1022 cl. 7.4	Stability of seatings which have variable geometry (rocking seat)	--	N/A	
EN 1022 cl. 7.1	EN 1022 cl. 7.5	Stability of seatings which have variable geometry (seats with extended footrest)	--	N/A	

Table 2

NOTE: Number of users for a piece of furniture for sitting = 1. (EN 1176-1:2008, cl. A.3.3)

TEST RESULTS according to PN-EN 60601-2-52:2010

Requirements according to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Real value	Test result	Comments
201.9.8.3.3 .3	V/I	Side rail strength and latch reliability (fig. 201.117)	--	N/A	30 000 cycles block/unblock
		Barrier latch test			
	V/I	a – Fatigue load on the barrier (E-F)	--	N/A	3000 cycles E-F 500N
	V/I	b - Fatigue load on the barrier (C-D)	--	N/A	3000 cycles C-D 500N
	V/I	c - Fatigue load on the barrier (A-B)	--	N/A	3000 cycles A-B A=500N, B=750N
	V/I	d - Static load on the barrier	--	N/A	1 x A,B,C,D,E,F
		Barrier test			
	V/I	a – Fatigue load on the barrier (E-F)	Conf.	Pos.	3000 cycles E-F 100 N
	V/I	b - Fatigue load on the barrier (C-D)	Conf.	Pos.	3000 cycles C-D 100 N
	V/I	c - Fatigue load on the barrier (A-B)	Conf.	Pos.	3000 cycles B B=100N
	V/I	d - Static load on the barrier	Conf.	Pos.	1 x A,B,C,D,E,F 100 N

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	--	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	Conf.	Pos.
	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 5
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	$t \leq 41^{\circ}\text{C}$ ■ 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

Requirements according to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Test result	Opinion	Comments
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	--	N/A	Mass of product below 20 kg
16	V/I. Measur.	Assistive products which support or suspend users	Conf.	Pos.	tested according to. EN 581-2, PN-EN 60601-2-52:2010
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	Conf.	Pos.	
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	--	N/T	
		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	

Requirements according to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Real value	Test result	Comments
		m - operator control adjustments			
		n - whether and how the assistive product can be folded or dismantled to assist in storage or transport			
		o - instructions regarding transport of the assistive product (e.g. in a car or aeroplane)			
		p - measured sound power level			
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	
		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	

Requirements according to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Real value	Test result	Comments
		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	<i>Note 1</i>

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

NOTE 3: During visual inspection before testing any visible defects that can have an effect on test results were not stated.

NOTE 4: Sample/object for testing was delivered to the Laboratory by the Orderer.

NOTE 5: The risk of corrosion that affects the safety of the users should be evaluated in the risk analysis.

CONCLUSIONS:

*Testing object **conforming** with requirements of:*

EN 581-2:2015

EN 1022:2005

PN-EN 60601-2-52:2010

PN-EN 12182:2012

- END -