

CENTRE FOR TESTING AND CERTIFICATION - MECH-TEST

Mechanical Laboratory

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Date 10.11.2021

TEST REPORT NO. *CBC-226/2021*

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Subject of testing:

Wall mounted folding support rail

Classification according to

PN-EN ISO 9999:2017-02: 18 18 06

Type / Model:

Wall mounted folding support rail, white, 76cm Art.-Nr.: 311676 Wall mounted folding support rail, white, 55cm

311655

Manufacturer:

MOBILEX A/S

Number of specimens: 2

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 according to PN-EN 12182:2012;

Test started: 30.09.2021

Test finished: 10.11.2021

Approved by:

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.

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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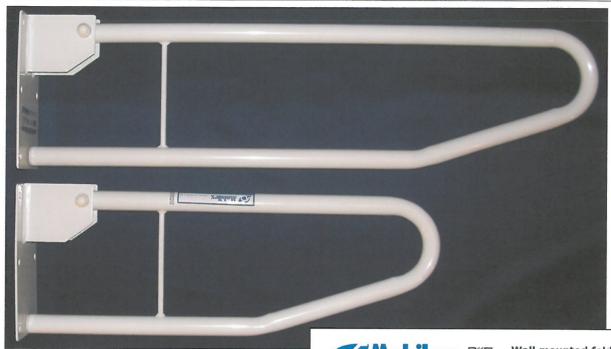
TESTING

NORMATIVE REFERENCES

PN-EN 12182:2012

Technical aids for disabled persons - General requirements and test methods

PHOTO OF PRODUCT









User weight ≤150 kg Loading force ≤ 80 kg











Wall mounted folding support rail (55 cm) REF 311655

User weight ≤150 kg

Loading force ≤ 80 kg







CHARAKTERISTICS OF PRODUCT

| 311676 760 mm | 311655 |
|----------------------|---|
| 760 mm | |
| 700 111111 | 550 mm |
| 80 kg | 80 kg |
| 120 kg | 120 kg |
| 1,93 kg | 1,63 kg |
| 25,5 mm | 25,5 mm |
| 200 x 100 x 3 mm | 200 x 100 x 3 mm |
| 190,0 mm | 189,0 mm |
| | 80 kg 120 kg 1,93 kg 25,5 mm 200 x 100 x 3 mm |

Material:

steel



V/I

11

Sterility

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| | | | | | | | Page: . | 3 of 6 | |
|--|---|--|--|---------|----------------|---|--------------|--|--|
| | | TEST R | ESULTS according to Pl | N-EN 1 | 2182 | : 2012 | | | |
| Requirement s according to clause | Test method according to clause | Checked | Checked characteristics/assemblies/parameters | | | | | 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 | A.S. 5.2. 5.4.2. A.S. 6.8.2.1. 9.4. B. 10. 22, 24 i EN 1441 VI Expected characteristics and technical documentation Clinic assessment V/I Technical support which can be dismantled V/I Single use connections V/I Boundary values of user weight V/I Immobilising means V/I, C5 Suitability of the product for people with cognitive impairment The presence of the description in the manufacturer's documentation Materials EN 60601-1-9 Recycling V/I, EN 59.2 Flammability V/I Upholstered parts, mattresses, bed bases and bedding V/I, EN 1021 Upholstered parts V/I, EN 597 V/I. EN 1021 Upholstered parts Woulded parts Noile95-11-10 NI SO 12952 V/I N 60695-11-10 NI SO 10993-1 Annex. D V/I Contaminants and residues V/I, EN ISO 22442-1 B.5.5.2 EN ISO 9227 Resistance to corrosion Emitted sound and vibration Noise and vibration Noise and vibration En ISO 3746 Sound levels and frequencies of audible warning devices Checked characteristics/assemblies/parameters N ISO 3746 Feeedback Checked Checked Characteristics/assemblies/parameters N ISO 3746 Feeedback N/A | | | | | Pos. | | |
| 4.3 | EN ISO 14155 | | | | | | N/T | (A. 2000) | |
| 4.4 | | | | | | | N/A | | |
| 4.5 | | | | | | | N/A | | |
| 4.6 | | | | | | Conf. | Pos. N/A | 100 | |
| 4.7 | | Checked characteristics/assemblies/parameters As, 5.2, 5.4.2 | | | | | | | |
| 4.0 | V/I, C5 | | | | ent | | N/T | | |
| 4.8 | | | | er's | | | N/T | | |
| | | | | | | | | | |
| 5.1 | EN 60601-1-9 | Recycling | | | | | N/T | | |
| 5.2 | V/I, B 5.2 | Flammability | The second secon | | | | N/A | | |
| 5.2.2 | V/I | Upholstered p | arts, mattresses, bed bases and beddi | ing | | | N/A | | |
| 5.2.3 | V/I, EN 1021 | Upholstered p | arts | | | | N/A | HO 1000000000000000000000000000000000000 | |
| 5.2.4 | V/I, EN 597 | V/I, EN 597 Mattresses and bed bases V/I. Bedding | | | | | N/A | | |
| 5.2.5 | V/I. EN ISO 12952 | V/I. Bedding EN ISO 12952 | | | | | N/A | | |
| 5.2.6 | EN 60695-11-1 | 1. Moulded parts 95-11-10 | | | | | N/A | | |
| 5.3 | | N ISO 12952 V/I. Moulded parts N 60695-11-10 N 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 | bu do | Cleaning | | | | N/T | 2 22000 | |
| 5.5 | V/I.,B.5.5.1 | biolc cal ons a | | | | | N/A | | |
| 3.3 | | Micro gi infectic | Animal tissue Animal tissue | | | | N/A | | |
| 5.6 | EN ISO 9227 | Resistance to | corrosion | | | | N/T | NOTE 1 | |
| 6 | | Emitted soun | d and vibration | | | | | 20 | |
| 6.1 | EN ISO 3746 B6 | Noise and vib | ration | | | | N/A | | |
| 6.2 | EN ISO 3746 | Sound levels a | and frequencies of audible warning d | levices | | | N/A | | |
| Require ments accordi ng to clause | | | | | Test result | | Comi | nents | |
| 6.3 | EN ISO 3746 | | | | N/A | | | | |
| 7 | EN 60601-1-2 7.2, 7.3, 7.4 | | | | N/A | | | | |
| 8 | | | | | N/A | | | | |
| 9 | | • | • | | N/A | 0 < 1100 | | | |
| 10 | V/I. Measur. | Surface tempera | ture | | N/A | t ⁰ ≤ 41 ⁰ C ■ requirement does not concern heat of direct solar radiation - PN-EN 12182,clause 10a ■ requirement concerns only persons we insensitiveness of skin (who do not fee heat) - PN-EN 12182,clause 10d | | | |
| 11 | V/I | Starility | | | NI/A | neu | y 111-1511 I | | |



N/A

| Mech | anical | al Laboratory of CBC Report no.: C | | | | | | | L |
|--|---|------------------------------------|---|---------------|----------------|-----------------------------------|-------------------|---|---------|
| Require ments accordi ng to clause | Test maccord | ing to | Checked characteristics/assemblies/parameters | Real value | Test result | Page: 4 of 6 Comments | | | |
| 12 | V/I. M | easur. | Safety of moving parts | | N/T | | | | |
| 13 | V/I. M | easur. | Prevention of traps for parts of the human body | | N/T | | | | |
| 14 | V/ | Ί | Folding and adjusting mechanisms | | N/T | | | 300000000000000000000000000000000000000 | *** |
| 15 | V/I. M | easur. | Carrying handles | | N/T | | | | |
| 16 | V/I. M | easur. | Assistive products which support or suspend users | Conf. | Pos. | | NO | TE 2 | |
| 17 | V/I. M | easur. | Portable and mobile assistive products | | N/A | | | | |
| 18 | V/I, I | 3 18 | Surfaces, corners, edges and protruding parts | Conf. | Pos. | | | | |
| 19 | В 1 | | Hand held assistive products | | N/A | | | 1880 110.51.17 | |
| 20 | B 2 | | Small Parts | Conf. | Pos. | | | | |
| | V/I. Me | | Stability | | | | | | |
| 21 | EN 600 | | | | N/A | | | | |
| 22 | В 22, | | Forces in soft tissues of the human body | | N/A | | | | |
| 23 | V/I EN 61 | | Ergonomic principles | | N/T | The requirements relate to the de | | | he desi |
| Require ments accordi ng to clause | Test method accordi ng to clause | | Checked characteristics/assemblies/ | /paramet | ters | | Real valu e | Test result | Con |
| 24 | V/I | Requi | rements for information supplied by the manufact | urer | | | | | |
| 24.1 | | Gener | | | | | | N/T | |
| 24.2 | | | ections for use | | | | | N/T | |
| 24.2.1 | V/I | | le Information | c . | | | | | |
| | | | formation on how to obtain the user information in a cople with visual,r eading orcognitive disabilities | format app | ropriate f | or use by | | N/T | |
| | | | l information shall as far as possible be available in Pic | ctogram | | | | N/T | |
| | | _ | description of the intended use and the intended enviro | | | | | N/T | |
| | | | aintenance instructions, if applicable; | , | | | | N/T | |
| | | aı | an assistive product is intended to be cleaned, a dead suitable cleaning materials, including precautions opplicable; | | | | | N/T | |
| | | f) if | an assistive product is intended to be disinfected, a cuitable materials, including any precautions needed to | | | | | N/T | |
| | | g) th m | ne overall dimensions (width, length and height) of the stillimetres, and its mass, expressed in kilograms, when oplicable, when it is folded or dismantled | assistive pr | oduct, exp | ressed in | | N/T | |
| | 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 | |
| 24.2.1 | | m | the assistive product is supposed to be used in combinanufacturer shall state to which products, and how this | can be dor | ne in a saf | e way; | | N/T | |
| | | oi fl | arning about dangerous combinations of devices (e.g f decubitus ulcers often only work on correct seat su ame resistant and non-flame resistant material; | rface) and | combinat | tions of | | N/T | 151 |
| | | de | list of accessories, detachable parts and materials the etermined as being intended for use with the assistive | product | | r has | | N/T | |
| | 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 | | |
| | | | perator control adjustments | | | | | N/T | |
| | | | hether and how the assistive product can be folded or transport | dismantled | to assist i | n storage | | N/T | |
| | | | structions regarding transport of the assistive product | (e.g. in a ca | ar or aerop | olane) | | N/T | |
| | | p) m | easured sound power level | | | | | N/T | |



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|--|--|--|-------------------|----------------|-------------|
| Require ments accordi ng to clause | Test method accordi ng to clause | Checked characteristics/assemblies/parameters | Real valu e | Test result | Com ment |
| 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 | |
| | | any adjustment or settings required before the assistive product can be used and information on how adjustments or settings affect the assistive product information on adjustment possibilities and the competence required to carry out these | | 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 | | 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 | |
| | | 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 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 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 | | N/T | |
| | | and for the replacement of parts. 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, | | N/T | |
| | | maintenance and calibration, including the frequency of such maintenance. The service information shall provide information for the safe performance of such | | N/T | |
| | | routine maintenance necessary to ensure the continued safe use of the assistive product. 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 | |
| | | | | | |



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|---|--|--|----------------------------|----------------|--------------|
| Require ments accordi ng to clause | Test method accordi ng to clause | Checked characteristics/assemblies/parameters | Real valu e | Test result | Com ments |
| 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 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 | 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 (80 kg)= 120 kg for a period of time 70 sec

Test result: Positive.

- The product was tested according to EN 1970:2000, clause 5.4.13, 5.4.14. Loading:
- Vertically downwards: load 750N, 1000 cycles
- Vertically downwards: load 1050N, 1 hour
- Perpendicular to the mounting bracket / wall; load 350N

Two products were tested.

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

