

# CENTRE FOR TESTING AND CERTIFICATION - MECH-TEST

## **Mechanical Laboratory**

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Date 12.01.2016

## TEST REPORT NO. *CBC-002/2016*

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Subject of testing:

Ramp

Classification according to

PN-EN ISO 9999:2011: 18 30 15

Type / Model:

SF 040

SF 090 SF 120 SF 150 SN.: --

2015677 2015527 2015787

Number of specimens: 4

Manufacturer:

MOBILEX A/S

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: 4.01.2016

Test finished: 12.01.2016

Approved by:

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. This test report shall be neither copied differently as in the whole nor be published without written consent of the Laboratory.



Mechanical Laboratory of CBC

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## **TESTING**

## NORMATIVE REFERENCES

PN-EN 12182:2012

Technical aids for disabled persons - General requirements and test methods

Serial no.

PHOTO OF PRODUCT



	<b>CHARAK</b> 1	TERISTICS	S OF PRODUCT		
Name of product:	SN	<b>[:</b>	Max. loading:	Mass of product:	
SF-040 Ramp			300 kg	3,845 kg	
		Dimension	ns:		
Composite:		450 x 354/379 x 51 mm			
Spread out:		450 x 710/731 x 27 mm			
Material:					

Produced



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TEST RESULTS according to PN-E	N	V 1	21	182	:	20	12	
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	TEST RESCETS decording to TIV-EIV 12102 : 2012								
Requirement s according to clause	Test method according to clause	Checked	d characteristics/assemblies/p	oarame	ters	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 cha	racteristics and technical documentar	tion		Conf.	Pos.		
4.3	EN ISO 14155	Clinic assessr	Clinic assessment						
4.4	V/I	Technical sup	Technical support which can be dismantled						
4.5	V/I	Single use co	Single use connections						
4.6	V/I	Boundary val	oundary values of user weight				Pos.		
4.7	V/I	Immobilising	nmobilising means				N/A		
	V/I, C5	Suitability of	the product for people with cognitive	e impairn	nent		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	40 3000 <b>-</b>				N/A		
5.2.2	V/I		Jpholstered parts, mattresses, bed bases and bedding				N/A		
5.2.3	V/I, EN 1021		Jpholstered parts				N/A		
5.2.4	V/I, EN 597	Mattresses and	d bed bases				N/A		
5.2.5	V/I. EN ISO 12952	Bedding					N/A	Visualis	
5.2.6	V/I. EN 60695-11-10	Moulded parts					N/A		
5.3	EN ISO 10993-1 Annex. D		formity and toxicity				N/T		
5.4	V/I	Contaminants					N/A		
	V/I.,B.5.5.1	ica and on	Cleaning		W-01100 - 70000	Conf.	Pos.		
5.5	V/I.,B.5.5.1	iolog ons a	Disinfection				N/A	28/1909	
3.3	V/I., EN ISO 22442-1 B.5.5.2	Microbiologica I infections and contamination	Animal tissue				N/A	TO THE STATE OF TH	
5.6	EN ISO 9227	Resistance to o	corrosion				N/T		
6		Emitted soun	d and vibration						
6.1	EN ISO 3746 B6	Noise and vibr	ation	\$277.87E \$22.5			N/A		
6.2	EN ISO 3746	Sound levels a	nd frequencies of audible warning de	evices			N/A	4	
Require ments accordi ng to clause	Test method according to clause	characteris	Checked tics/assemblies/parameters	Real value	Test result		Comments		

ments accordi ng to clause	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 <sup>0</sup> ≤ 41 <sup>0</sup> 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	2 2 3 3 7 3 3 7 3 7 3 7 3 7 3 7 3 7 3 7



			oratory of CBC	1	Repo	rt no.: (		02/201 4 of 15	6	
Require ments accordi ng to	accor	nethod ding to use	Checked characteristics/assemblies/parameters	Real value	Test result		Com	ments		
clause 12	V/I, N	leasur.	Safety of moving parts	Conf	D	N/A	ota in ga	nica man		
13		leasur.	Prevention of traps for parts of the human body	Conf.	Pos. Pos.		lote in service manual lote in service manual			
14		//I	Folding and adjusting mechanisms	Conf.	Pos.		te in service manual			
15	V/I. M	leasur.	Carrying handles	Conf.	Pos.	1	loading 80 N			
16	V/I. M	leasur.	Assistive products which support or suspend users	Conf.*)	Pos.		1,5x300	kg=450kg les, 300k		
17	V/I. M	leasur.	Portable and mobile assistive products		N/A		ooo cyc	103, 3000	8	
18	V/I,	B 18	Surfaces, corners, edges and protruding parts	Conf.	Pos.					
19	В	19	Hand held assistive products		N/A					
20	В	20	Small Parts	Conf.	Pos.					
21	V/I. M EN 60	0601-1	Stability		N/A					
22	B 22		Forces in soft tissues of the human body		N/A					
23	EN 6		Ergonomic principles		N/T	The requi	irements relate to the desig			
Require ments accordi ng to	Test method accordi ng to		Checked characteristics/assemblies/parameters				Real valu	Test result	Com	
clause 24	clause V/I	Requi	rements for information supplied by the manufactu	ror			e			
24.1		Gener		11 61				N/T		
24.2		Instru	ctions for use					N/T		
24.2.1	V/I		le Information					11/1		
		a) information on how to obtain the user information in a format appropriate for use by people with visual,r eading orcognitive disabilities								
		<ul> <li>all information shall as far as possible be available in Pictogram</li> <li>a description of the intended use and the intended environment;</li> <li>maintenance instructions, if applicable;</li> </ul>						N/T		
								N/T 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;								
		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		
		mı apı	overall dimensions (width, length and height) of the a llimetres, and its mass, expressed in kilograms, when i plicable, when it is folded or dismantled	t is ready fo	r use an	l, if		N/T		
4.2.1	V/I	any	mass expressed in kilograms if the assistive product removable parts that has a mass which is heavier tha	n 10 kg:				N/T		
		ma	he assistive product is supposed to be used in combina nufacturer shall state to which products, and how this	can be done	in a safe	wav.		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		
		det	st of accessories, detachable parts and materials the ermined as being intended for use with the assistive p	roduct		has		N/T		
		pro effe	programmable controller is fitted, information or gramming, the competence required to carry out the ects on performance	the methor programmi	d of ng and tl	ne		N/T		
	-		erator control adjustments					N/T		
		or t	ether and how the assistive product can be folded or di ransport					N/T		
	-	o) inst p) mea	ructions regarding transport of the assistive product (easured sound power level	.g. in a car	or aeropl	ane)		N/T		
		P) 11102	asured sound power level					N/T		



Mech	Mechanical Laboratory of CBC Report no.: (						
Require	Test	P	Page: 5 of 15				
ments accordi ng to clause	method accordi ng to clause	Checked characteristics/assemblies/parameters	Real valu e	Test result	Com		
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			
1		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		$\frac{N}{T}$			
		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			
		<ul> <li>i) instructions on dismantting and re-assembly of the assistive product or any removable parts;</li> </ul>		N/T			
		<ul> <li>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;</li> </ul>		N/T			
		<ul> <li>k) a warning if surface temperatures can increase / decrease when exposed to external sources of heat or cold (e.g. sunlight, outdoor environment);</li> <li>1) a warning if the assistive product might disturb the operation of devices in its</li> </ul>		N/T			
		environment that emit electromagnetic fields (e.g. alarm systems of shops, automatic doors, etc.);		N/T			
		<ul> <li>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);</li> </ul>		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 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		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		N/T			
		maintenance and calibration, including the frequency of such maintenance.  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			



Mech	ıanical		CBC-002/2016 Page: 6 of 15				
Require ments accordi ng to clause	Test method accordi ng to clause	Checked characteristics/assemblies/parameters	Real valu	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 1		

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.

#### **CONCLUSIONS:**



Mechanical Laboratory of CBC

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## **TESTING**

## NORMATIVE REFERENCES

PN-EN 12182:2012

Technical aids for disabled persons - General requirements and test methods

## PHOTO OF PRODUCT

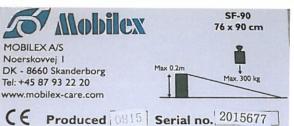




Name of product: SF-090 Ramp

aluminum, steel, plastic

Composite :
Spread out:
Material:



SN: 2015677	Max. loading: 300 kg	Mass of product. 7,595 kg
Dimensions		
902 mm x 401	/426 mm x 103 mm	
902 mm x 766	/791 mm x 113 mm	

Sterility

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		TEST R	ESULTS according to P	N-EN	12182	: 2012		
Requirement s according to clause	Test method according to clause	Checke	d characteristics/assemblies/p	parame	ters	Test result	Opinion	Comments
4.1	4.8, 5.2, 5.4.2 5.5, 6, 8.2.1, 9. 10, 22, 24 i E 1441	4,					N/T	
4.2	V/I		racteristics and technical documenta	tion		Conf.	Pos.	
4.3	EN ISO 1415						N/T	10000000
4.4	V/I		pport which can be dismantled			Conf.	Pos.	
4.5	V/I		igle use connections			Conf.	Pos.	
4.6	V/I		oundary values of user weight			Conf.	Pos.	
4.7	V/I	Immobilising					N/A	
4.8	V/I, C5		the product for people with cognitive		nent		N/T	
4.0		The presence of the description in the manufacturer's documentation  Materials					N/T	
<i>-</i> 1	Table Procedures Control of the Cont							
5.1	V/I, B 5.2	Flammability					N/T	
5.2.2	V/I, B 5.2 Plaining of the V/I Upholstered parts, mattresses, bed bases and bedding				N/A			
5.2.3	V/I, EN 102	i i i i i i i i i i i i i i i i i i i					N/A	
5.2.4	V/I, EN 597	A CONTROL OF THE PROPERTY OF T					N/A	
	V/I.						N/A	
5.2.5	EN ISO 1295	2					N/A	
5.2.6	V/I. EN 60695-11-1 EN ISO 10993-					N/A		
5.3	Annex. D	21010810411 001	nformity and toxicity			N/T		
5.4	V/I	Contaminants	and residues			N/A		
	V/I.,B.5.5.1	ogica s and trion	Cleaning				Pos.	
5.5	V/I.,B.5.5.1	iolog ons a	Disinfection				N/A	
3.3	V/I., EN ISO 22442-1 B.5.5.2	Microbiolog	Animal tissue				N/A	
5.6	EN ISO 9227	Resistance to	corrosion				N/T	
6		Emitted soun	d and vibration					
6.1	EN ISO 3746 B6						N/A	
6.2	EN ISO 3746	Sound levels a	nd frequencies of audible warning de	evices			N/A	
Require ments accordi ng to clause	Test method according to clause	characteris	Checked tics/assemblies/parameters	Real value	Test result	Comments		ients
6.3	EN ISO 3746	Feeedback			N/A			
7	EN 60601-1-2 7.2, 7.3, 7.4	Electromagnetic	compatibility		N/A	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
8		Electrical safety	IV/A					
9	V/I		ge, leakage, and ingress of liquids		N/A		374700003440000	
10	V/I. Measur.	Surface temperat	rface temperature  N/A  N/A				ct solar radio 12182,clar ment concern veness of ski	not concern heat of ation - PN-EN use 10a as only persons with n (who do not feel
11	V/I	Sterility			NIA	heat)	- PN-EN 12	182,clause 10d



N/A

Mech	ianical Labo	oratory of CBC		Report no.: CBC-002/2016 Page: 9 of 15			
Require ments accordi ng to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Real value	Test result	Comments		
12	V/I. Measur.	Safety of moving parts	Conf.	Pos.	Note in service manual		
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	Conf.	Pos.	loading 160N		
16	V/I. Measur.	Assistive products which support or suspend users	Conf.*)	Pos.	loading 1,5x300kg=450kg, 70sek 1000 cycles, 300kg		
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  m, Elastic deformation – 6 mm, sustained deform		N/T	The requirements relate to the design process		

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.

### **CONCLUSIONS:**



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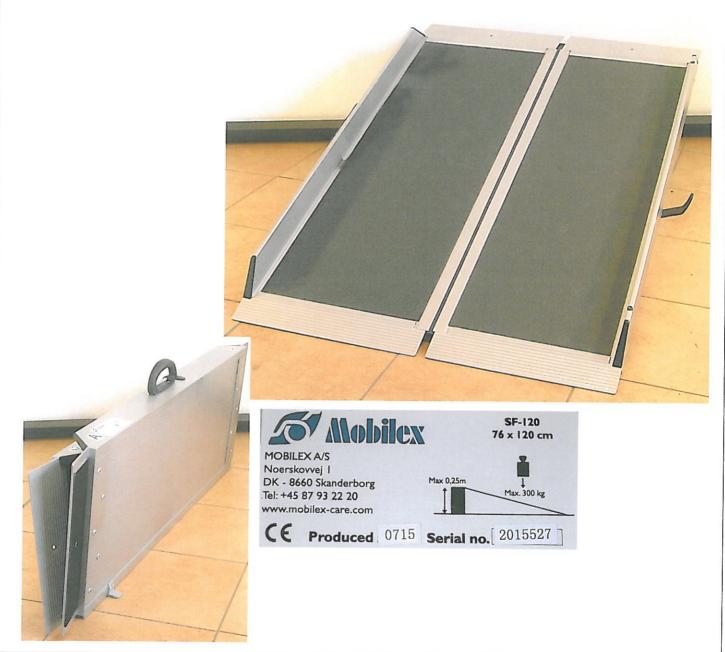
## TESTING

## NORMATIVE REFERENCES

PN-EN 12182:2012

Technical aids for disabled persons - General requirements and test methods

PHOTO OF PRODUCT



	<b>CHARAKTERISTICS</b>	OF PRODUCT				
Name of product: SF-120 Ramp	SN: 2015527	Max. loading: 300 kg	Mass of product: 9,795 kg			
	Dimension	:				
Composite:	1200 mm x 40	1200 mm x 403/425 mm x 102 mm				
Spread out:		1200 mm x 766/791 mm x 110 mm				
Material:						
aluminum, steel, plastic						



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		TEST R	<b>ESULTS</b> according to P	N-EN	12182	: 2012				
Requirement s according to clause	Test method according to clause	Checke	d characteristics/assemblies/	parame	ters	Test result	Opinion	Comments		
4.1	4.8, 5.2, 5.4.2. 5.5, 6, 8.2.1, 9. 10, 22, 24 i EN	4,					N/T			
4.2	V/I	Expected cha	racteristics and technical documenta	tion		Conf.	Pos.			
4.3	EN ISO 1415	5 Clinic assessi	nent				N/T			
4.4	V/I	Technical sur	Technical support which can be dismantled Conf. Pos.							
4.5	V/I	Single use co	nnections	110-28 to 10 mm		Conf.	Pos.			
4.6	V/I	Boundary val	ues of user weight			Conf.	Pos.			
4.7	V/I	Immobilising	mmobilising means							
	V/I, C5	Suitability of	the product for people with cognitiv		N/A N/T					
4.8			of the description in the manufactur				N/T			
		documentatio	documentation							
		Materials								
5.1	EN 60601-1-9	7 8					N/T			
5.2	V/I, B 5.2	Flammability					N/A			
5.2.2	V/I		parts, mattresses, bed bases and bedd	ing			N/A			
5.2.3	V/I, EN 102		Upholstered parts					N/A		
5.2.4	V/I, EN 597		d bed bases			N/A				
5.2.5	V/I. EN ISO 12952					N/A				
5.2.6	V/I. EN 60695-11-1						N/A			
5.3	EN ISO 10993- Annex, D	Biological cor	nformity and toxicity			N/T				
5.4	V/I	Contaminants	and residues	***************************************						
	V/I.,B.5.5.1	ca nd	Cleaning			Conf.	Pos.			
	V/I.,B.5.5.1	V/I.,B.5.5.1 Disinfection				N/A				
5.5	V/I., EN ISO 22442-1 B.5.5.2	Microbiologica Linfections and contamination	Animal tissue				N/A			
5.6	EN ISO 9227	Resistance to	Corrosion				) I (T)			
6			d and vibration				N/T			
	EN ISO 3746	Noise and vibr								
6.1	B6		3.9				N/A			
6.2	EN ISO 3746	Sound levels a	nd frequencies of audible warning d	evices			N/A			
Require ments accordi ng to clause	Test method according to clause	characteris	Checked tics/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, spillag	ge, leakage, and ingress of liquids		N/A					
10	V/I. Measur.	Surface temperat	ure		N/A	t <sup>P</sup> ≤ 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	neut)	1 14-DIV 121	os,ciuise 10a		



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Require ments accordi ng to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Real value	Test result	Comments	
12	V/I. Measur.	Safety of moving parts	Conf.	Pos.	Note in service manual	
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	Conf.	Pos.	loading 196 N	
16	V/I. Measur.	Assistive products which support or suspend users	Conf.*)	Pos.	loading 1,5x300kg=450 kg, 70sek. 1000 cycles, 300 kg	
17	V/I. Measur.	Portable and mobile assistive products	7221	N/A	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.		
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  m, elastic deformation – 8 mm, sustained deformation		N/T	The requirements relate to the design process	

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.

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### **CONCLUSIONS:**



	<b>CHARAKTERISTICS</b>	OF PRODUCT				
Name of product: SF – 150 Ramp	SN: 2015787	Max. loading: 300 kg	Mass of product.			
	Dimensions	s:				
Composite:	1500 mm x 39	1500 mm x 399/424 mm x 105 mm				
Spread out:	1500 mm x 76	1500 mm x 763/789 mm x 78/105 mm				
Material:						



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TEST RESULTS according to PN-EN 12182: 2012

		TESTR	ESULTS according to I	'N-EN	12182	: 2012		
Requirement s according to clause	Test method according to clause	Checked characteristics/assemblies/parameters			ters	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				N/T			
4.2	V/I	Expected cha	Expected characteristics and technical documentation			Conf.	Pos.	
4.3	EN ISO 1415	5 Clinic assessi	Clinic assessment				N/T	
4.4	V/I	Technical sup	Technical support which can be dismantled			Conf.	Pos.	
4.5	V/I	Single use co				Conf.	Pos.	
4.6	V/I	Boundary val	Boundary values of user weight			Conf.	Pos.	
4.7	V/I	Immobilising	Immobilising means				N/A	
4.8	V/I, C5	the state of the s	Suitability of the product for people with cognitive impairment  The presence of the description in the manufacturer's  documentation				N/T N/T	
		Materials					1 1 1 1 1 1	
5.1	EN 60601-1-9	Recycling					N/T	
5.2	V/I, B 5.2	Flammability					N/A	277
5.2.2	V/I	Upholstered p	arts, mattresses, bed bases and bedo	ding			N/A	
5.2.3	V/I, EN 102						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 60695-11-1						N/A	
5.3	EN ISO 10993- Annex. D	-1 Biological conformity and toxicity					N/T	
5.4	V/I	Contaminants	Contaminants and residues				N/A	
	V/I.,B.5.5.1	nd nd	Cleaning  Disinfection  Animal tissue			Conf.	Pos.	
	V/I.,B.5.5.1	2.1 ologi nas an natice					N/A	
5.5	V/I., EN ISO 22442-1 B.5.5.2	Microbi I infectic contami					N/A	
5.6	EN ISO 9227	Resistance to o	corrosion				N/T	
6		Emitted soun	d and vibration				1772	
6.1	EN ISO 3746 B6	Noise and vibr				N/A		
6.2	EN ISO 3746	Sound levels a	nd frequencies of audible warning o	levices			N/A	
Require ments accordi ng to clause	Test method according to clause		Checked tics/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		300 at 41-	
8		Electrical safety	000000000000000000000000000000000000000		N/A			7,000
9	V/I		e, leakage, and ingress of liquids		N/A			
10	V/I. Measur.	Surface temperat	ure		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 skin (who do not feel heat) - PN-EN 12182,clause 10d		
11	V/I	Sterility			N/A			,



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Require ments accordi ng to clause	Test method according to clause	Checked characteristics/assemblies/parameters	Real value	Test result	Comments
12	V/I. Measur.	Safety of moving parts	Conf.	Pos.	Note in service manual
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	Conf.	Pos.	loading 240N
16	V/I. Measur.	Assistive products which support or suspend users	Conf.*)	Pos.	loading 1,5x300kg=450kg, 70sek. 1000 cycles, 300kg
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
*) Defo	rmation – 10 i	nm, elastic deformation – 10 mm, sustained defor	mation – 0	mm	

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.

### **CONCLUSIONS:**

