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Test report

Test report relating to electrically powered wheelchairs and scooters according to the European wheelchair standard EN 12184, concerning the scooter product name: Movinglife™, type: ATTO, manufactured by Moving Life Ltd.

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Date	December 7, 2015
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1 Introduction

1.1 Purpose

The tests have been performed in order to establish whether or not the product meets the requirements of the European Standard EN 12184 [1].

1.2 Description of the sample(s)

Manufacturer	Moving Life Ltd.
Name product	ATTO Product number AT01
Version	1.0
Max. user weight	tested with 100 kg

Trademark and type of motor(s)	CT01-TB, Brushless DC motor*
Trademark and type of controller	MT01-MM, Brushless DC Motor Driver*
Maximum speed	6,4 Km/h
Class	A
Propulsion	front wheel drive
Code according to ISO 9999	12 21 24 electric-motor-driven, manual steering
Method of propulsion/steering ISO 7176-26	4.1.9 scooter
Configuration of seat	non-detachable, horizontally adjustable (as whole seat unit), rigid upholstered cushion, plastic,
Configuration of back rest	non detachable, horizontaly adjustable (as whole seat unit), rigis upholstered, plastic
Configuration of arm rest	full length armrest, folded
Configuration of leg rest	not applicable, footplate
Type of head rest	not applicable
Back rest angle adjustment (α)	not adjustable
Seat plane angle adjustment (ϕ) or body support system angle adjustment ($\Delta\phi$)	not adjustable
Leg to seat surface angle adjustment (ß)	not applicable
Arm rest angle adjustment (δ)	not adjustable
Foot rest to leg angle adjustment (γ)	not applicable
Seat surface height adjustment	by user/attendant in steps
Seat depth	380 mm (ISO 7176-22)
Seat width	370 mm (ISO 7176-22)
Total length	470 mm (ISO 7176-22)
Total width	370 mm (ISO 7176-22)
Total height	330 mm (ISO 7176-22)
Trademark/type of front tyre	MovingLife / 203 x 57
Trademark/type of rear tyre	MovingLife / 228 x 57
Trademark/type of battery	BT25-IE, Li-Ion 48V, 5.2 Ah*
Trademark/type of battery charger	SPBC4802A, 54.6V, 2A*

* names and pictures are later provided by Moving Life

Picture 1: product label.

Picture 2: Battery label*

Picture 3: Charger label*

* Later provided by the manufacturer.

1.3 Sampling procedure

TÜV Rheinland B.V., acting as Test Laboratory, has had no influence on the selection of the sample. The first samples were test-worthy and were received on August 17, 2015 by the manufacturer.

1.4 Application

The request for testing was submitted by the manufacturer on March 26, 2015, order number: 00379.

1.5 Method of testing

All tests have been performed according to the European Standard EN 12184 [1].

1.6 Used test equipment

Device	Manufacturer and Type
Amp-hour meter	BCM - VD 00562-bcm 98
Digital multi-meter	Tektronix - DMM916
Double foot dummy	Homemade
Dummy seat 100 kg	Homemade
Dummy seat 75 kg	Homemade
Sound meter	Flus - ET -958
Weight 25 kg	Inogon
ISO drummer	Homemade
Handheld tachometer	Teclock - Type L
Angle plate (1)	Homemade
Angle plate (2)	Homemade

High-pressure pump	Airstrike - BFP-01
IEC 60601-1 test finger	Homemade
ISO dummy + feet, 100 kg	Homemade
ISO dummy + feet, 75 kg	Homemade
ISO dummy + feet, life test	Homemade
Calibration weight 25 kg	Homemade
Tipping blocks	Homemade
Children rlg-dummy	Homemade
Small slope	Vink Lisse - 411
Dynamometer push/pull impact	AE - MW520
Laptop PC	Dell - Lenovo T400
Photometer	KMT - Pocketlux 2
Hygrometer	Novasina - MS1
Measuring wheel	Homemade
Pendulum 10 kg	Homemade
Pendulum 25 kg	Homemade
Power supply	Delta Elektronica - SM 35 - 45
Power supply	Delta Elektronica - SM 35 - 45
RLG-measuring dummy	Homemade
Measuring tape 5m	Stanley - 33-684
Sliding rule wheelchair lab.	Mitutoyo
Steel ruler 500 mm	Mitutoyo - 50cm
Static impact set-up	Homemade
Exit slope	Homemade
Floor plate, fall test	Homemade
Footrest height setting-up block 50	Homemade
Weighing platform	Homemade
Set square	Homemade
Friction block	Homemade

1.7 Put out to contract

The first climatic test for electric wheelchair concerning the ISO 7176-9:2009 has been carried out under full responsibility of TÜV Rheinland Nederland B.V. by Thales Nederland B.V. located in Hengelo The Netherlands.
The second climatic test for electric wheelchair concerning the ISO 7176-9:2009 has been carried out by QualiTech Compliance Engineering Environmental & Mechanical Lab. located in Petach Tikva Israel. This report under accreditation was supplied by the manufacturer.

1.8 Privacy statement

Due to privacy reasons, the names of involved personnel that executed the tests, are not disclosed in the report. However, this information is available on internal work sheets, test forms etc. in the project file.

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1.9 Notifications, accreditations, designations

TÜV Rheinland Nederland B.V. has been accredited by the Dutch Accreditation Council (RvA) as ISO 17025 Test Laboratory (nr. L 484) and ISO 17065 Certification Body (nr. C078).

1.10 Report revision

The difference between the first report 89207808 dated November 20, 2015 and the second report 89207808-2 dated December 7, 2015 are some textual adjustments.

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2 Test summary

Test results after performing all applicable tests according to the European Standard EN 12184 [1].

Par.	Headline	Assessment (pass/Fail/N.a.)
6	General requirements	pass
8	Wheelchair performance	pass
9	Component properties	pass
10	Propulsion and braking systems	pass
11	Operations	pass
12	Electrical systems	pass
13	Information supplied by the manufacturer	pass

For detailed test results and photo's is referred to Appendix A and B.

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3 Remarks on the test results

Chapter nr. *	Description of the requirement	Remark
8.2	Static, impact and fatigue strength Back rest impact	8.4 and 8.8 (ISO 7176-8) The first supplied ATTO had armrests but the manufacturer excluded this from the options. The second ATTO was without arm rests. 9.3 (ISO 7176-8) The height of the backrest is < 320 mm making this requirement expire.
10.2.1 (sub b)	The wheelchair shall have a running brake which, when operated after the wheelchair has been put into freewheel mode, shall bring the wheelchair to a stop.	The ATTO did not have a running brake while the freewheel mode is activated. However the ATTO is a class A scooter and at the front wheel/freewheel mode is placed a sticker. 
10.2.1 (sub g)	Parking brakes shall be operable when the wheelchair is in freewheel mode.	Equal to chapter 10.2.1 (sub B) above.
10.3	Freewheel device: Be within the reach space shown in Figure 1, if the wheelchair is intended to be operated by the occupant.	Equal to chapter 10.2.1 (sub B) above.

*) *This chapter number corresponds to chapter in "test overview of electrically powered wheelchair in accordance with ISO 7176-8", see Annex C.*

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4 Conclusion

The electrically powered scooter, **Movinglife™**, type: **ATTO**, version 1.0 **meets** the requirements as stated in the European Standard EN 12184 [1] for class **A**.
The test results exclusively relate to the inspected object.

The conclusion is that the **product shows** compliance with these requirements.

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5 References

[1] European Standard EN 12184:2014(E),
Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods -
European Committee of Standardization, March 2014.

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6 Signature

Author	Signature
Mr. H. Fokkenrood Expert Medical products	
Approved by	**Signature**
Mr. R. P. van Egmond Ad interim Business Field Manager products	

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Appendix A Photo sheet

Photograph of the tested sample, product name: **Movinglife™**, type: **ATTO** version **1.0.**

Picture 4: Closed front side

Picture 5: Closed back side

Picture 6: driving front side

Picture 7: driving right side

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Appendix B Detailed test results

Sample nr: MT15.55780.01 Results for type: ATTO, version 1.0 Req. nr. Description of the requirement	Required	Value of the test	pass/ fail /n.a
6 **General requirements**			
Must conform to the requirements of EN 12182 for all under-mentioned sub-requirements			
6 (sub1) **Intended performance and technical documentation** (EN 12182, 4.2)		available	
6 Confirmation of sufficient strength and durability	Must be confirmed.	available	pass
6 Intended performance described in technical documentation, if appropriate	Must be described, if appropriate	available	pass
6 References described in technical documentation, if appropriate	References available, if appropriate	not appropriate	n.a.
6 (sub 2) **Aids that can be dismantled** (EN 12182, 4.4)	If intended that it can be dismantled: no hazard caused by incorrect re-assembling possible	cannot cause hazard	pass
6 (sub 3) **Single use fasteners** (EN 12182, 4.5)	If intended that it can be dismantled: no single use fasteners used	no single use fasteners	pass
6 (sub 4) **Biocompatibility and toxicity** (EN 12182, 5.3) Materials which come into contact with the human body shall be assessed for biocompatibility using the guidance in EN ISO 10993-1 and shall fulfil the following requirements.			
6 The assessment shall take into account the intended use and contact by those involved in user care or transportation and storage of the product.	Must be assessed.	available	pass
6 The assistive products shall be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the assistive product	Must be assessed.	available	pass
6 (sub 5) **Contaminants and residues** (EN 12182, requirement 5.4) Substances which may leak from an aid (e.g. oil, grease and acid) shall either:			
6 be assessed for biocompatibility conform guidance in EN ISO 10993-1 **OR**	Result of the assessment must be available **OR** protection available	not applicable	n.a.
6 provided with protection against hazardous substance(s).		not applicable	
6 (sub 6) **Infection and microbiological contamination** (EN 12182, 5.5)			
6 Cleaning and disinfection	If intended to be cleaned: methods and materials in product-info.	cleaning: available	pass
	If intended to be disinfect-ted: methods and materials in product-info.	disinfection: not applicable	n.a.
Animal tissue	If it is intended to be cleaned by automatic washing machine, procedure must be described in user manual	not applicable	n.a.
6 (sub 7) **Overflow, spillage, leakage**			
6 Overflow (EN 12182, 9.1)	Overflow may not cause safety hazard(s).		n.a.

Sample nr: MT15.55780.01 Results for type: ATTO, version 1.0 **Req. nr.** **Description of the requirement** **Required**			**Value of the test**	**pass/ fail /n.a**
6	Spillage (EN 12182, 9.2)	Spillage may not cause safety hazard(s).		n.a.
6	Leakage (EN 12182, 9.3)	Leakage may not cause safety hazard(s).	assessment available	pass
6	Ingress of liquids (EN 12182, 9.4)	Ingress of liquids may not cause safety hazard(s).	assessment available	pass
6 (sub 8)	**Safety of moving parts**			
6	Moving parts that can cause an unintended safety hazard shall either: (EN 12182, 12.1)			
6	be provided with guards (removable with the use of tools only) **OR** have gaps which comply with the applicable requirements for adults: **OR** have provisions to prevent run off or jump out (cord, chain or belt drive(s)) or must be provided with guards (removable with the use of tools only) **OR** have a control device which stops movement immediately when not operated. **OR** have a detecting device which stops movement automatically and immediately when a safety hazard occurs	Must have guards. Removable with tools. **OR** Finger traps: ≤ 8 mm or ≥ 25 mm Foot traps: ≤ 35 mm or ≥ 120 mm Head traps: ≤ 120 mm or ≥ 300 mm Genitalia traps: ≤ 8 mm or ≥ 75 mm **OR** May not come out of there guiding device(s). Used guards must be removable with tools. **OR** Movement stops when device is released. **OR** Must detect safety hazard(s). Stops movement automatically	sufficient protection not applicable < 8 mm or > 25 mm - mm - mm - mm not applicable not applicable not applicable	pass pass n.a. pass n.a.
6	Parts subject to mechanical wear likely to result in a safety hazard (EN 12182, 12.2)	Must be accessible (for inspection).	not applicable	n.a.
6	Emergency stopping functions (EN 12182, 12.3) If there is a risk for the user to be squeezed or a single fault appearing that might create a safety hazard there shall be an emergency stop as specified in EN ISO 13850 together with the following requirements:	The assistive product shall be designed to prevent accidental damage or stopping movements. The user shall be able to reach the emergency stop easily, and stop the dangerous situation within one action. The stopping device shall maintain the equipment in a safe position, but not interfere with other critical functions.	available available available	pass pass pass

Sample nr: MT15.55780.01 Results for type: ATTO, version 1.0 Req. nr. Description of the requirement		Required	Value of the test	pass/ fail /n.a
		The emergency stopping device shall maintain the assistive product in a stopped position until it is released by a designated procedure.	available	pass
		The designated procedure for the release of the emergency stop shall require two independent actions.	available	pass
		A safe stopping distance shall be considered in the risk analyses.	available	pass
6 (sub 9)	**Prevention of traps for parts of human body** (EN 12182, 13) Holes in and clearances between stationary parts (if accessible by user or attendant) shall either:			
6	**V-shaped openings**			
	The risk of entrapment in V-shaped openings shall be assessed by the manufacturer. Particular guidance can be found in B.13.2.			n.a.
6	have a safe distance which complies with the applicable requirements for adults:	Finger traps: ≤ 8 mm or ≥ 25 mm Foot traps: ≤ 35 mm or ≥ 100 mm Head traps: ≤ 120 mm or ≥ 250 mm Genitalia traps: ≤ 8 mm or ≥ 75 mm	- mm - mm - mm - mm	n.a.
6	must have, if a hazardous situation can occur, a warning and instructions on safe use of the aid included in the manufacturer's instructions.	Must have warnings Must have instructions	not applicable	n.a.
6 (sub 10)	Folding and adjustment mechanisms			
6	The mechanisms shall be capable of being securely locked when the aid is in any fixed working configuration. (EN 12182, 14.2)	Must be securely locked	always securely locked	pass
6	Folding and adjustment mechanisms shall either: (EN 12182, 14.3)			
6	Be provided with means to protect the user from trap and or squeeze hazards OR have gaps which comply with the applicable requirements for adults: OR have a warning and instructions on how to operate the aid safely in the manufacturer's instructions (if hazardous situations can occur only)	Must have guards. OR Finger traps: ≤ 8 mm or ≥ 25 mm Foot traps: ≤ 35 mm or ≥ 120 mm Head traps ≤ 120 mm or ≥ 300 mm Genitalia traps: ≤ 8 mm or ≥ 75 mm. OR Must have warnings. Must have instructions.	not applicable - mm - mm - mm - mm warnings included instructions included	pass n.a.
6 (sub 11)	Surfaces, corners and edges (EN 12182, 18)			

Sample nr: MT15.55780.01 Results for type: ATTO, version 1.0				
Req. nr.	**Description of the requirement**	**Required**	**Value of the test**	**pass/ fail /n.a**
	If not required for the intended function of an aid, all accessible edges, corners and surfaces shall be smooth and free from burrs and sharp edges	Must be smooth. Free from burrs. Free from sharp edges.	all parts are smooth not applicable no sharp edges	pass
	If not required for the intended function, aids shall not have (unprotected) projections	Free from unprotected projections.	no projections	pass
6 (sub 12)	Clinical evaluation (EN 12182, 4.3) A clinical evaluation shall be done for all assistive products. If, as part of the product conformity assessment, the clinical evaluation requires a clinical investigation, the clinical investigation. A clinical evaluation shall always be done before performing a clinical investigation.	shall conform to the requirements of EN ISO 14155-1 and EN ISO 14155-2	sufficient protection	pass
6 (sub 13)	Ergonomic principles (EN 12182, 23) An assistive product shall be designed to the ergonomic principles set out in EN 614-1 taking into account the special needs of the person with a disability for whom the assistive product is intended. An assistive product may be used not only by whom it is primarily intended for, but also by an assisting person. The ergonomic principles set out in EN 614-1 shall apply to all involved persons. Grips, handles and pedals shall suit the functional anatomy of the user, according to the intended use and meet with the following requirements:	The distance between any handle requiring an operating force of more than 10 N and any construction part of the assistive product shall not be less than 35 mm; The distance between any upper surface of a pedal (in its operating position) and any other part of the assistive product shall have a vertical toe clearance of not less than 75 mm; The diameter of any operating handles and/or knobs requiring an operating force of more than 10 N shall be between19 mm and 43 mm; For assistive products operated from a standing position, pedals shall be placed not more than 300 mm above the surface of the floor; For assistive products operated from a standing position, hand operated controls shall be placed at a height of 800 mm to 1 200 mm above the surface of the floor; Handles for pushing and/or pulling shall be placed at a minimum height of 900 mm.	< 35 mm < 10 N - mm . 19 mm and < 43 mm ≥ 10 N - mm - mm	pass n.a. pass n.a. n.a. n.a.
7	Preparation for testing			
7.1	General			
	Settings according ISO 7176-22:2000			pass
8	Wheelchair performance			

8.1.1	General		
	The loaded wheelchair shall meet the driving performance requirements specified in Table1 and Table 2 for the type class of the wheelchair as specified in Clause 5.		pass

Degrees and direction	Braking method	Maximum speed	Speed before braking	Braking distance	
°		Km/h	Km/h	mm	
0° backwards	Release	5.04	3.88	600	pass
0° backwards	Stop	4.93	3.85	600	pass
0° forwards	Release	6.89	6.52	1103	pass
0° forwards	Stop	6.88	6.48	1096	pass
6° backwards	Release	5.12	4.11	1244	pass
6° backwards	Stop	5.12	4.17	1269	pass
6° forwards	Release	7.23	6.75	2299	pass
6° forwards	Stop	7.22	6.74	2296	pass

8.1.2.1	The wheelchair shall be capable of climbing at a speed not less than 2 km/h: -The applicable rated slope for the type class of wheelchair specified in Table1, or -The rated slope specified by the manufacturer, whichever is greater. The wheelchair passes the test specified in 8.1.2.2 if it achieves or exceeds a speed of 2 km/h after travelling 5 m up the slope.	At a slope of 6°	pass
8.1.3	Ground unevenness		
8.1.3.2	The wheelchair shall be capable of driving when any of its wheels is raised to a height specified in Table 1 for ground unevenness.	Height = 10 mm	pass
8.1.4	Maximum downhill speed.		
8.1.4.1	The wheelchair shall not exceed 125% of its maximum speed on the horizontal, when driving down – the applicable rated slope for the type class of wheelchair specified in Table 1, or The rated slope specified by the manufacturer, whichever is greater.	Slope of 0° = 6.88 m Slope of 6° = 7.23 m	pass
8.1.5	Dynamic stability		
8.1.5.1	The dynamic response score of the wheelchair shall be 2 or 3 as specified in Table A.1 of ISO 7176-2:2001 when tested on – The applicable rated slope for the type of wheelchair specified in Table1, and – the rated slope specified by the manufacturer.	Score at 6°:	pass
	For rearward dynamic stability chapter 8.2 (ISO 7176-2):	Starting forwards = 3	
	chapter 8.3 (ISO 7176-2):	Stopping forwards = 3	
	chapter 8.4 (ISO 7176-2):	Braking backwards = 3	
	For forward dynamic stability chapter 9.2 (ISO 7176-2):	Braking forwards = 3	
	For dynamic stability in lateral directions chapter 10.2 (ISO 7176-2):	N.a.	
8.1.6	Obstacle climbing and descending		
8.1.6.1	The wheelchair shall be cable of climbing and descending obstacles of the height specified in Table 1 for the type class of the wheelchair without any part of the wheelchair other than wheels or a kerb climbing device contacting the obstacle or the test plane.	AT a height of 18 mm	pass
	Chapter 7.1 no run up, (ISO 7176-10) :	= 22 mm	
	Chapter 7.2 run up, (ISO 7176-10) :	= 22 mm	
	Chapter 7.3 no run up, (ISO 7176-10) :	= 18 mm	
	Chapter 7.4 run up, (ISO 7176-10) :	= 22 mm	

	Chapter 7.5 test sequence forwards, (ISO 7176-10) : Chapter 7.6 descending rearwards, (ISO 7176-10) : Chapter 7.7 manufacturer's instructions, (ISO 7176-10) :		N.a. = 22 mm N.a.	
8.1.7	Static stability			
8.1.7.1	The wheelchair shall meet or exceed the minimum requirements for static stability specified in Table 1 for the type class of the wheelchair. A "least stable" and "most stable" refer to the positioning of the antitip devices			pass

Stability direction		
Forward	Front wheels locked	6°
	Front wheels unlocked	6°
Rear	Rear wheels locked	6°
	Rear wheels unlocked	6°
	Antitip devices a	n.a.
Sideways	Left	6°
	Right	6°

8.1.8	Maximum speed			
8.1.8.1	The maximum speed of the wheelchair when travelling forwards and travelling in reverse on the horizontal shall not exceed the maximum speed requirements specified in Table 1 for the type class of the wheelchair. Maximum speed horizontally : Maximum speed reverse :		 6.6 km/h 4.9 km/h	pass
8.1.9	Distance range			
8.1.9.1	The theoretical continuous driving distance range for the wheelchair shall not be less than the requirement specified in Table 1 for the type class of the wheelchair. Ebat= 231 Wh. Lengths test track = 50 m. Used energy clockwise = 8 w. Used energy counter clockwise = 8 w. Number of labs = 20.72		 231*(50*(20.72))/16. Distance = 14957 m	pass
8.2	Static, impact and fatigue strength			
8.2.1	The wheelchair shall conform to the requirements of ISO 7176-8:1998. With the exception that wheelchairs of class A are not required to be tested as specified in ISO 7176-8:1998, 10.5, drop test. (tested with a load of **100** kg). Details:	Must comply with all requirements: - static strength tests - impact strength tests - fatigue tests	complies with ISO 7176-8 meets the requirements meets the requirements meets the requirements	pass
	8.4, Arm rests: downward	used load - N	n.a.	
	8.5, Foot rests: downward	used load 1000 N	pass	
	8.6, Tipping levers	used load - N	n.a.	
	8.7, Handgrips	used load - N	n.a.	
	8.8, Arm rests: upward	used load - N	n.a.	
	8.9, Foot rests: upward	used load - N	n.a.	
	8.10, Push handles, upward	used load - N	n.a.	
	9.3, Back rest impact	used: pendulum (-°)	n.a.	

	9.4, Handrim impact 9.5, Castors impact 9.6, Foot rests impact 10.4, Double drum test 10.5, drop test	used: pendulum (-°) used: pendulum (-°) used: pendulum (49°) 200,000 cycles 6,666 cycles (or 1/30 of cycles of 2-drum test)	n.a. n.a. pass pass n.a. (class A)	
8.3	Wheelchairs for use as seats in motor vehicles			
	Intended us as seat in a motor vehicle by an occupant of a mass not less than 22 kg or greater.	Conform the performance of ISO 7176-19:2008 with the following modifications. 4.1.2, 5.2.1 a, 5.2.2 e.	not applicable	n.a.
8.4	Climatic performance			
	The wheelchair shall conform to the requirements of ISO 7176-9:2009	This requirement includes the one stated in ISO 7176-14:2008, 13.1. It is not necessary to duplicate the test.	Tested by: QualiTech Report No.: 20151018-1044 Date: 28-10-2015	pass
9.1	Foot supports, leg supports and arm supports			
9.1.1	Foot supports shall have means for positioning the user's feet at the required height.	Have means for positioning the feet.	means available:	pass
9.1.1	Foot supports shall have means for preventing the user's feet from sliding backwards.	Have means for preventing the feet.	not applicable:	n.a.
9.1 .1 (a)	Incorporate a means to locate it securely in any intended operating position	Means to fix securely in any operating position for:	means available	pass
9.1 (b)	be adjustable in increments not exceeding 25 mm	Adjustment steps not exceeding 25 mm.	in steps of mm	pass
9.1 (c)	be accessible and operable: by the occupant/assistant or both in accordance with the manufacturer's intended use of the wheelchair.	Accessible and operable Within the area of reach by occupant/assistant	accessible and operable within the users reach	pass
9.1 (d)	Be within the reach space shown in Figure 1, and			
9.1 (e)	be operable without the use of tools The ability to make adjustments without the use of tools is not required.	Operable without the use of tools	without use of tools	pass
9.1 (f)	Where the wheelchair has separate foot support which have a gap between them or the possibility of a gap being formed when they are loaded, means to prevent the occupant's feet from sliding into the gap shall be provided, or			n.a.
9.1 (g)	When the foot supports are tested in accordance with 9.1.2.2, any gap between them shall meet the requirement for safe distances between stationary parts specified in EN 12182.			n.a.
9.2	Component mass			
9.2	If the wheelchair is intended to be dismantled for storage or transportation, any component that requires moving or handling that has a mass greater than 10 kg shall be provided with suitable handling devices (e.g. handles). The manufacturer shall provide information indicating the points where such components can be lifted and describing how they shall be handled during disassembly, lifting, carrying, and assembly to reduce risks to the person or persons moving or handling them.		Front half = 12 kg Rear half = 16,2 kg	pass

9.3	Pneumatic tyres			
9.3	Pneumatic tyres (if fitted with pneumatic tyres)	Shall have the same type of valve connections on all tyres. Readily accessible Tires or rims shall be marked with the maximum pressure in kPa or bar or PSI	no pneumatic tyres	n.a.
9.4	Anterior pelvic support			
9.4	Shall have provision for an anterior pelvic to be fitted Shall be available as option And can be used with that provision	Shall have a provision. Shall available as option Shall be used with that provision	provision available (option)	pass
9.5	Resistance to ignition			
9.5.1	Upholstered composite parts shall be tested as specified in EN1021-2:2006 or ISO 8191-2:1988 (composites of cover and filling, with or without a support base or interliner)	Progressive smouldering ignition and flaming ignition shall not occur	No textile used	n.a.
9.5.2	Foam Materials shall be tested as specified in EN 1021-2:2006 or ISO 8191-2:1988 (foams with form all or parts of a seat, back support, postural-, arm- or lower leg support, with or without an integral skin)	Progressive smouldering ignition and flaming ignition shall not occur	No foam used	n.a.
9.5.3	Other parts shall be tested as specified in EN 1021-2:2006 or ISO 8191-2:1988 (sling seats, sling backs, belts, restraint harnesses, foot supports, and clothing guards the material of each of them)	Progressive smouldering ignition and flaming ignition shall not occur		n.a.
9.5.4	Power and control systems			
9.5.4 (a)	Either of the following options a or b shall apply. The manufacturer shall adopt appropriate means to eliminate or reduce as far as reasonably practicable the risk of a hazardous situation developing from the ignition of any part of the power and control system of the wheelchair. The manufacturer shall use the process specified in EN ISO 14971:2012 to manage that risk.			pass
9.5.4 (b)	The power and control system of the wheelchair shall meet the requirements of ISO 7176-14:2008, 9.7, resistance to ignition. Based on report		Accepted test report from FORMOSA CHEMICALS & FIBRE CORP PLASTICS DIV, number: E162823, dated: 2007-02-26	pass
10	Propulsion and braking systems			
10.1.1 a	Means for operating brakes shall:			
10.1 (sub a1)	be accessible and operable by the occupant or an assistant or both in accordance with the manufacturer's intended use of the wheelchair;	Brakes shall be within the users and/or assistants reach.	within the occupants/assi	pass

10.1 (sub a2)	be within the reach space shown in Figure 1, if the wheelchair is intended to be operated by the occupant;	Brakes shall be within the users reach.	within the occupants reac	pass
10.1 (sub a3)	be within the reach space shown in Figure 3, if the wheelchair is intended to be operated solely by an assistant;	Brakes shall be within the assistant reach.	within the assistant reach	pass
10.1 (sub a4)	have operating forces for engaging and disengaging as stated in Table 1 when tested in accordance with 10.1.2	single finger 5 N one hand 13.5 N hand +arm 60 N foot, push 100 N foot, pull 60 N	- N)* - N)* < 60 N)* - N)* - N)* * if applicable	pass
10.1 (sub b)	If one of more braking levers are fitted, used on bicycles/ and mopeds:			
10.1 (sub b1)	for wheelchairs with a maximum occupant mass not greater than 150 kg, the force applied to each lever to hold the loaded wheelchair stationary on the rate slope shall not exceed 60 N;	Be ≤ 60N	N	n.a.
10.1 (sub b2)	for wheelchairs with a maximum occupant mass greater than 150 kg, the force applied to each lever to hold the loaded wheelchair stationary on the rate should not exceed 60 N;	Be ≤ 60N	N	n.a.
10.1 (sub b3)	the handgrip width of such brake levers when no force is applied, measured 15 mm from the end of the brake lever, shall not be greater than 100 mm and should not be greater than 80 mm (see Figure 4).	Hand grip width shall ≤ 100 mm and should not be greater than 80 mm	N	n.a.
10.1 (sub c)	Means for releasing parking brakes shall be protected against activation caused by accidental contact.			n.a.
10.2	Braking functions			
10.2.1 (sub a)	The wheelchair shall have a running brake which operates independently of tyre wear and tyre inflation pressure and which does not exceed the maximum stopping distance specified in Table 2 when tested in accordance with 10.2.2.1. Braking distance at a speed of 6.87 km = 1096 m.		Speed = 6.87 km Braking dist. = 1.019 m	pass
10.2.1 (sub b)	The wheelchair shall have a running brake which, when operated after the wheelchair has been put into freewheel mode, shall bring the wheelchair to a stop.			n.a.
10.2.1 (sub c)	The wheelchair shall have an automatic brake, which operates independently of tyre wear and tyre inflation pressure and which is operated by releasing the control device to achieve a zero speed command (e.g. spring loaded disc brake).			pass
10.2.1 (sub d)	The wheelchair shall have a parking brake which operates independently of tyre wear and tyre inflation pressure(e.g. drum brake in wheels, spring loaded disc brake)			pass
10.2.1 (sub e)	Parking rakes shall meet the parking brake effectiveness requirement in Table 1 when tested in accordance with 10.2.2.2.			pass
10.2.1 (sub f)	Parking brakes shall be operable when there is no power from the battery supplying the drive system,			pass
10.2.1 (sub g)	Parking brakes shall be operable when the wheelchair is in freewheel mode			n.a.

10.2.1 (sub h)	If they are subject to wear, parking brakes shall have provision for adjustment and/or replacement as specified by the manufacturer.			pass
10.2.1 (sub i)	If the wheelchair is fitted with arm supports that can be moved or removed to enable transfer, when tested in accordance with 10.2.2.3, engaged parking brakes shall not have parts that protrude above the level of the occupied seat.			pass
10.2.1 (sub j)	When parking brakes are tested in accordance with 10.2.2.4, no parking brake mechanism shall move from the pre-set position and no component or assembly of parts shall show visible signs of cracks, breakages, gross deformations, free play, loss of adjustment or any other damage that adversely affects the function of the wheelchair.			n.a.
10.2.1 (sub k)	Following testing of the parking brake in accordance with 10.2.2.4, parking brakes shall meet the parking brake effectiveness requirement in Table 1 when tested again in accordance with 10.2.2.2.			n.a.
10.3	Freewheel device			
	The wheelchair shall be fitted with a freewheel device that shall, -be accessible and operable by the occupant or an assistant or both in accordance with the manufacturer's intended use of the wheelchair, -be within the reach space shown in Figure 1, if the wheelchair is intended to be operated by the occupant, -be within the reach space shown in Figure 3, if the wheelchair is intended to be operated solely by an assistant; -have operating forces for engaging and disengaging that do not exceed those stated in Table 1, -be operable without detaching any parts, -not depend on the battery power supplying the motor drive system, -have two defined positions including velar indication of freewheel mode and drive mode, -prevent use of the wheelchair's drive system, if the freewheel device is activated. - freewheel mode shall be protected against activation caused by accidental contact		- > 27 N - < 47N	- pass - n.a. - pass - pass - pass - pass - pass - pass - pass
11	Operations			
11.1	The wheelchair shall be designed to facilitate ease of operation by user/attendant as specified the manufacturer instructions	Facilitate ease of operation by user/attendant	ease of operation	pass
11.2	Controls intended for operation by the occupant			
11.2	Controls intended to be operated by the occupant while seated shall be within the occupant reach space shown in figure 1. The following controls, if fitted, are included: — on/off switch or key, — speed regulator, — speed pre-setting, — running brake, — parking brake, — audible warning device, — direction indicator, — direction switch, — control device, — manual steering controls, — lighting controls,	Controls shall be within the users reach.	within the occupants reac - pass - pass - pass - pass - pass - pass - pass - pass - pass - pass - pass	pass

	— seating adjustments, — detachable components to facilitate safe transfers into and out of the wheelchair, — steering controls, — freewheel device.		- pass - pass - pass - pass	
11.3	Controls operated by an attendant			
11.3	Controls intended to be operated by an assistant shall be within the assistant reach space shown in figure 3.	Controls shall be within the assistant reach.		n.a.
11.4	Assistant control, push handles and handgrips			
11.4 (sub 1)	Switches intended to be operated by an assistant while driving the wheelchair shall be attached to an assistant control unit. When an assistant control unit is fitted, 1. the unit shall be positioned behind the wheelchair's back support, between 900 mm and 1200 mm from the floor to the centre of the operating means for the control device (e.g. joystick handle), and 2. there shall be a means to support the assistant's hand or hands used to operate the control device.			n.a. n.a.
11.4 (sub 1)	3. When push handles are fitted, no part of the wheelchair shall lie within a space to the rear of the wheelchair bounded by the following: - a plane at 85° to the horizontal, that touches the rearmost points of the push handles as shown in Figure 6; - two planes not less than 350 mm apart equidistant from a vertical plane parallel to the forward direction of travel that bisects the wheelchair, unless the intended occupant is a child; - the horizontal test plane.			n.a.
11.4 (sub 1)	4. When the wheelchair is fitted with steering and / or manoeuvring handgrips for use by an assistant, the handgrips shall be at least 75 mm in length and between 20 mm and 50 mm in diameter.		Hand grip = - mm	n.a.
11.4 (sub 1)	5. When manoeuvring handgrips are fitted with controls that are intended to be used by being gripped by one hand, the handgrip width when no force is applied shall not be greater than 100 mm and should not be greater than 80 mm see Figure 4.			n.a.
11.5	Operating forces			
11.5 (sub 1)	All controls, except for means to operate brakes, shall have operating forces for engaging and releasing that do not exceed those started in Table 1 when tested in accordance with 11.5.2.	single finger 5 N one hand 13.5 N hand +arm 60 N foot, push 100 N foot, pull 60 N.	- N)* - N)* < 60 N)* - N)* - N)* * if applicable	pass

11.5 (sub 1)	Turning knobs operated by one hand shall have: A max. force (Nm) of 0,05 times the diameter of the knob (mm) when the knob is ≥ 25 mm where the force is transmitted by friction, and A max. force (Nm) of 0,025 times the diameter of the knob (mm) when the knob is < 25 mm to archive the minimum performance of the system or device.	Turning knobs shall: F= 0,05 x D knob if D knob is ≥ 25 mm Diam. Knob = - mm F = 0,05 D = - Nm F= 0,05 x D knob if D knob is < 25 mm Diam. Knob = - mm F = 0,025 D = - Nm	F = - Nm F = - Nm	n.a n.a
11.6	Seating adjustments for tilt and recline systems			
11.6 (sub 1)	If specified that the seating can be adjusted by an assistant while user is seated: - attendant/user shall not have to lift a mass present a safety hazard	- attendant/user shall not have to lift a mass present a safety hazard		n.a.
11.6 (sub 2)	Controls intended to be operated by the occupant while seated shall be within the users reach.	Controls shall be within the users reach.		n.a.
12	Electrical powered ancillary equipment			
12.1	- The wheelchair shall conform to the requirements of ISO 7176-14:2008, except as specified in 9.5.4. - The wheelchair and battery charger shall conform to the requirements of ISO 7176-21:2009. - In addition. Wheelchairs that include an on-board battery charger shall conform to the applicable electrical requirements of EN 60601-1:2006			- pass - pass - n.a.
12.2	Circuit protection			
	- The driving, braking and steering functions shall not be affected by the operation of the means of protection of any other circuit. - Lights, direction indicators and hazard warning flasher functions shall not be affected by the operation of the means of protection of any other circuit.			- pass - pass
12.3	Battery chargers			
12.3.a	Battery chargers for wheelchairs shall conform to the requirements of ISO 7176-14:1997 that apply to battery chargers, together with the following provisions: - battery chargers shall indicate when charging is in progress and when charging is complete			pass
12.3.b	battery chargers shall have the capability of charging batteries discharged to 70 % of their nominal voltage;			pass
12.3.c	battery chargers shall operate without the need for intervention or supervision apart from connecting and turning on at the start of charging and turning off and disconnecting at the end of charging;			pass
12.3.d	carry-on and on-board battery chargers shall meet the environmental protection requirements of IPX4 when tested in accordance with EN 60529:1991 and shall meet the Class II Test Voltage requirements of EN 60335-1:2012 following the test.			n.a.
12.4	Charging connector			
	The wheelchair shall have a charging connector that is readily accessible and operable by the occupant or an assistant or both in accordance with the manufacturer's intended use of the wheelchair.			pass

12.5	Battery enclosures and containers			
	Battery enclosures and containers shall provide protection so that it should not be possible for liquids dropping from above to enter into them and onto any cell or battery they contain.			pass
12.6	Emergency stop			
	The wheelchair shall be fitted with one or more emergency stop devices to enable actual or impending danger to be averted. Each emergency stop device shall: — be clearly identifiable, clearly visible and quickly accessible by the intended operator, and — stop the hazardous process as quickly as practicable, without creating additional risks.			 - pass - pass
	- Once active operation of the emergency stop device has ceased following a stop command, that command shall be sustained by the wheelchair until that engagement is specifically overridden. It shall not be possible to engage the device without triggering a stop command. It shall be possible to disengage the device only by an appropriate operation, and disengaging the device shall not restart the wheelchair but only permit restarting. - The emergency stop function shall be available and operational at all times, regardless of the operating mode. - Emergency stop devices shall be a back-up to other safeguarding measures and not a substitute for them.			- pass - pass - pass
12.7	Lighting			
	Wheelchairs intended by the manufacturer for outdoor use shall be supplied with integral lighting suitable for the operations concerned where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity.			n.a.
12.8	Switching off while driving			
	If the wheelchair is switched off while driving on the horizontal, it shall come to a stop within the maximum stopping distances specified in Table 2.			pass
12.9	Electronic programmable systems			
	- Software that is embedded in the wheelchair or is an integral part of the wheelchair, and the malfunction of which could give rise to a hazardous situation, shall be developed and maintained in accordance with EN 62304:2006. - This requirement does not apply to software produced before the date of withdrawal of EN 12184:2009, but it does apply to software modifications that are made after that date.			- pass - pass
13	Information supplied by the manufacturer			
13.1	General			
13.1	Each wheelchair shall be provided with documentation and labelling that conform to the requirements in EN 12182 and ISO 7176-15:1996.	Must conform to EN 12182 and ISO 7176-15	according to EN 12182 according to ISO 7176-15	pass
	In addition, the manufacturer shall provide the documentation in three separate sections: pre-sale, user and service information as specified in 13.2, 13.3 and 13.4. These may be provided as separate printed documents or in other forms of media to meet the needs of individual occupants or their assistants.	Provide in 3 separate sections	3 separate sections	pass
	For the requirements in 13.2 and 13.3, unless otherwise specified, all linear dimensions shall be expressed in millimetres and all masses shall be expressed in kilograms.	Dimensions in mm and kg		pass

13.2	Pre-sale information			
	In addition to the requirements of 13.1, pre-sale information shall include the following:			
	a) information on how to obtain the user information in a format appropriate for use by visually impaired people;	In manual	information available	a) pass
	b) a description of the intended occupant of the wheelchair, including the occupant's mass and any specific requirements for the occupant's functional capability, visual ability and cognitive ability suitable for operating the wheelchair safely in its intended environment;	In manual	information available	b) pass
	c) the intended operator (occupant, assistant or both);	In manual	information available	c) pass
	d) a description of the intended use and the intended environment;	In manual	information available	d) pass
	e) the type class of the wheelchair: Class A, Class B or Class C;	In manual	information available	e) pass
	f) the overall dimensions (width, length and height) of the wheelchair and its mass when it is ready for use and, if applicable, when it is folded or dismantled;	In manual	information available	f) pass
	g) if the overall dimensions of the wheelchair when it is ready for use exceed the values recommended in A.1.1, a clear statement that the wheelchair is larger than the recommended dimensions;	In manual	information available	g) n.a.
	h) the minimum width of corridor in which the wheelchair can be turned to face the opposite direction;	In manual	information available	h) pass
	i) the rated slope, expressed in degrees;	In manual	information available	i) pass
	j) the standard options that are available for the wheelchair;	In manual	information available	j) pass
	k) the type(s) of tyres that can be used on the wheelchair;	In manual	information available	k) pass
	l) operator adjustments;	In manual	information available	l) pass
	m) if the wheelchair can be dismantled or has any removable parts, the mass of the heaviest part;	In manual	information available	m) pass
	n) information concerning whether the removal of parts or accessories intended by the manufacturer to be removed without the use of tools will have adverse or beneficial effects on the wheelchair;	In manual	information available	n) pass
	o) information on whether or not the wheelchair is intended to be used as a seat in a motor vehicle, and whether and how this depends on the standard options referred to in j);	In manual	information available	o) pass
	p) information on whether the unoccupied wheelchair is suitable for land and/or air transport;	In manual	information available	p) pass
	q) the theoretical continuous driving distance range, expressed in kilometres, that the wheelchair can travel under its own power on the horizontal when tested in accordance with ISO 7176-4:2008, with the addition of a	In manual	information available	q) pass

	note explaining that the distance will be reduced if the wheelchair is used frequently on slopes, rough ground or to climb kerbs, etc.; This additional requirement may be reduced to some degree if an accurate charge level indicator is fitted.			
	r) the maximum height of kerb which the wheelchair can descend safely;	In manual	information available	r) pass
	s) if a programmable controller is fitted, information on the method of programming, the competency required to carry out the programming and the effects it can have on driving performance	In manual	information available	s) pass
13.3	User information			
	User information shall be provided by the manufacturer with each wheelchair. Further copies shall also be available for any subsequent user of the wheelchair. User information shall contain all pre-sale information and the following:		provided	
	a) the unique identification number of the wheelchair or information on the location of the unique identification number on the wheelchair;	In manual	information available	a) pass
	b) any adjustment or settings required before the wheelchair can be used and warnings of how adjustments or settings affect stability;	In manual	information available	b) n.a.
	c) where applicable, information on any adjustments that can be made and the competency required to carry out these adjustments;	In manual	information available	c) pass
	d) instructions on operation of all controls, including brakes;	In manual	information available	d) pass
	e) instructions on how to engage and disengage the drive system;	In manual	information available	e) pass
	f) the wheelchair manufacturer's recommended tyre pressure(s), expressed in kPa, bar or PSI;	In manual	information available	f) n.a.
	g) instructions for dealing with tyre punctures, where pneumatic tyres are fitted;	In manual	information available	g) n.a.
	h) the battery type and nominal voltage;	In manual	information available	h) pass
	i) instructions for battery maintenance;	In manual	information available	i) pass
	j) instructions for operating the battery charger, including warnings regarding any potential safety hazards (e.g. a possibility of gas accumulating in the charging area, use of the wrong type of battery charger);	In manual	information available	j) pass
	k) if required by the risk analysis, instructions for fitting an additional emergency stop device where the intended occupant has an impairment which could restrict their ability to operate one;	In manual	information available	k) n.a.
	l) instructions on whether and how the wheelchair can be folded to assist in storage or transport;	In manual	information available	l) pass

	m) instructions on dismantling and re-assembly of the wheelchair or any removable parts;	In manual	information available	m) pass
	n) instructions regarding transport of the wheelchair when it is unoccupied (e.g. in a car or aeroplane);	In manual	information available	n) pass
	o) the masses of parts of the wheelchair that are expected to be handled during dismantling, reassembly, or carrying;	In manual	information available	o) pass
	p) 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;	In manual	information available	p) pass
	q) if the manufacturer specifies that the wheelchair is intended for use as a seat in a motor vehicle, the method of attaching wheelchair tie down and occupant restraints, and recommendations about suitable tie down and restraint systems;	In manual	information available	q) n.a.
	r) if the manufacturer specifies that the wheelchair is not intended for use in the motor vehicle, a warning to that effect, together with the symbol shown in Figure 7;	In manual	information available	r) n.a.
	s) instructions on how to obtain and fit the optional anterior pelvic support (see 9.4) if it is not supplied with the wheelchair;	In manual	information available	s) pass
	t) the positions of points intended to carry additional loads;	In manual	information available	t) pass
	u) instructions for preparing the wheelchair for long-term storage (e.g. longer than four months) and for preparing it for use afterward;	In manual	information available	u) pass
	v) a warning that the wheelchair might disturb the operation of devices in its environment that emit electromagnetic fields (e.g. alarm systems of shops, automatic doors, etc.);	In manual	information available	v) pass
	w) a warning that the driving performance of the wheelchair can be influenced by electromagnetic fields (e.g. those emitted by portable telephones, electricity generators or high power sources);	In manual	information available	w) pass
	x) a warning that the stopping distance on slopes can be significantly greater than on level ground;	In manual	information available	x) pass
	y) a warning that surface temperatures can increase when exposed to external sources of heat (e.g. sunlight);	In manual	information available	y) pass
	z) a warning for trapping hazards (e.g. pinch points);	In manual	information available	z) pass
	aa) a warning if driving characteristics can be adjusted outside the limits specified in Table 1 and Table 2;	In manual	information available	aa) pass
	bb) a warning if the adjustments of seating or wheel positions can be set outside safe limits;	In manual	information available	bb) pass
	cc) if the overall width or overall length of the wheelchair when it is ready for use exceed the applicable values	In manual	information available	cc) pass

	recommended in A.1.1, a warning concerning access to emergency escape routes;			
	dd) the level of resistance to ignition of materials and assemblies;	In manual	information available	dd) pass
	ee) information on the recycling of used batteries and of the wheelchair;	In manual	information available	ee) pass
	ff) if the characteristics of the wheelchair (including occupant as applicable) exceed the limits specified in Annex M of the Technical Specification for Interoperability relating to Accessibility for Persons with Reduced Mobility (PRM-TSI), a statement to that effect (see Annex D);	In manual	information available	ff) n.a.
	gg) information on how to find out about product safety notices and product recalls, for example by ensuring the supplier has up-to-date contact information;	In manual	information available	gg) pass
	hh) the expected service life of the wheelchair; ii) the name and address of the manufacturer; jj) the name and address of the authorised representative, where the manufacturer does not have a registered place of business in the European Union.	In manual	information available	hh) pass
13.4	Service information			
	The service information shall contain all the pre-sale, user information and instructions necessary for the maintenance, adjustment and repair of the wheelchair and for the replacement of parts		information available In manual	pass
13.5	Labelling			
	In addition to the requirements of 13.1, the manufacturer shall apply permanent labelling for the following:			
	a) devices for disengagement of the drive system, showing engaged and disengaged positions, including a warning that the drive system should be re-engaged before an occupant is left unattended or attempts to operate the wheelchair;	Clearly marked Showing positions Warning available	Marked clearly Showing positions Warning available	pass
	b) for wheelchairs where the intended use includes use as a seat in a motor vehicle, the position of attachment points for wheelchair tie-down and occupant restraint systems (WTORS);	Clearly marked	Marked clearly	n.a.
	c) for wheelchairs not intended to be used as a seat in a motor vehicle, a warning to that effect, including the symbol shown in Figure 7 with a diameter not less than 15 mm, in the same location as the labelling required by ISO 7176-	Clearly marked	Marked clearly	pass

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	15:1996; d) for battery chargers that are not on-board chargers, information and connection details specified in Clause 9 of ISO 7176-14:1997; e) for Class A wheelchairs not intended for use outdoors, a warning to that effect	Clearly marked Clearly marked	 Marked clearly	n.a. pass

§ 24.2.2	User information User information shall be provided by the manufacturer with each assistive product. Information shall contain all pre-sale warnings and information's and the following as applicable for each assistive product:			
	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;	In manual	information available	a) pass
	b) the intended user;	In manual	information available	b) pass
	c) any adjustment or settings required before the assistive product can be used and information on how adjustments or settings affect the assistive product;	In manual	information available	c) n.a.
	d) information on adjustment possibilities and the competence required to carry out these adjustments;	In manual	information available	d) pass
	e) instructions on operation of all controls;		information available	e) pass
	f) the battery type and nominal voltage;	In manual	information available	f) pass
	g) instructions for battery maintenance;	In manual	information available	g) pass
	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);	In manual In manual	information available	h) pass
	i) instructions on dismantling and re-assembly of the assistive product or any removable parts;	In manual	information available	i) pass
	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;	In manual	information available	j) pass
	k) a warning if surface temperatures can increase / decrease when exposed to external sources of heat or cold (e.g. sunlight, outdoor environment);	In manual	information available	k) pass
	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.);	In manual	information available	l) pass
	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)	In manual	information available	m) pass
	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;	In manual	information available	n) pass
	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	In manual	information available	o) pass
	p) the level of resistance to ignition of materials and assemblies;	In manual	information available	p) pass
	q) information on the recycling of used batteries and other parts of the assistive product;	In manual	information available	q) pass
	r) expected lifetime of the assistive product.	In manual	information available	r) pass

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§ 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.	In manual	information available	pass
	The service information shall contain all the pre-sale information and the user information.	In manual	information available	pass
	The service information shall be sufficiently detailed concerning preventive inspection, maintenance and calibration, including the frequency of such maintenance.	In manual	information available	pass
	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.	In manual	information available	pass
	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.	In manual	information available	pass
§ 24.3	labelling - In addition to the requirements of 24.1, the manufacturer shall apply permanent labels for the year of production for the product;		information available	pass
	- Detachable parts of an assistive product with a mass of more than 10 kilograms shall be marked with the actual mass on the part;		information available	pass
	- Symbols for use in the labelling of medical devices shall be in accordance with NEN EN ISO 15223.		information available	pass
§ 25	Packaging The hazards that can be caused by inadequate protective packaging shall be assessed in the risk analysis			n.a.
	EN 1041 Information supplied by the manufacturer of medical devices			
§ 4 § 4.1	Requirements General Product information and labelling shall be part of risk management procedures.		In risk manual	pass

§ 4.2	Units, symbols and colours - Units used shall be SI units as specified in ISO 1000 or any other legal units. - Symbols and safety-related identification colours shall be explained in the information supplied unless they are taken from harmonized standards."		pass pass
§ 4.3	Language and country identifiers - If the manufacturer decides to identify the language used in the information provided, for example to indicate to users the appropriate language in a multilingual document, this shall be done using the language codes given in ISO 639-1 and/or the plain text of the language (e.g. "English"). - If the manufacturer decides to identify the country in the information provided, for example to indicate to users the appropriate customer service contact details for their country, this shall be done using the country codes given in EN ISO 3166-1 and/or the plain name of the country (e.g. "France").		pass pass
§ 4.4	Dates Any human-readable date shall be expressed in the format YYYY-MM-DD, YYYY-MM or YYYY, in accordance with ISO 8601.		pass
§ 4.5 § 4.5.1	Device nomenclature Identifiers of nomenclature When it is required to include the identification of the generic device group or the device category in the information supplied with the device, this may be done using a nomenclature that is in compliance with EN ISO 15225.		n.a.
§ 4.5.2	Device common terms When it is appropriate to identify collective terms for medical devices in the information supplied, for example common technology or common materials of construction, this shall be done using the terms and codes set out in CEN/TR 15133		n.a.
§ 4.5.3	Batch code; lot number; batch number; lot code These shall consist of alphanumeric characters but may also be presented by other means, for example by using machine-readable codes.		n.a.
§ 5.1 § 5.1.1	General Safe and effective use of the device" - Any means of provision of information with medical devices shall take into account the intended users, the conditions of use and any issues specific to individual device types that are necessary for the safe and effective use of the device. This shall apply regardless of whether the specific requirements listed below apply to the device. - The appropriate way of providing information shall be based on a risk assessment and in line with the training, experience and education of the intended users.		pass pass
§ 5.1.2	5.1.2 Address required under medical devices directives - All medical devices which are placed on the market and put into service within the Community, shall contain the name or trade name and address of the manufacturer in the information supplied by the manufacturer. - When the manufacturer does not have a registered place of business in the Community, the information shall contain in addition the name and address of the authorized representative. - For devices covered by the MDD, the name or the trade name and address of the manufacturer shall appear on the label and in the instruction for use if provided with the device. When the manufacturer does not have a registered place of business in the	Available Available Available	pass pass pass

	Community, the label, or the outer packaging, or instructions for use shall contain, in addition, the name and address of the authorized representative. - For devices covered by the AIMDD, the name and address of the manufacturer shall appear on the sterile pack and the sales packaging and in the instruction for use. When the manufacturer does not have a registered place of business in the Community, the sales packaging and the instructions for use shall contain, in addition, the name and address of the authorized representative. - The address to be used shall be the same as the address of the manufacturer and/or the authorized representative as their registered place of business. The address shall be the same as the address used on the declaration of conformity, in relevant certificates and in the European database for medical devices. - The full address used shall contain the following elements insofar as they are available in the address system of the country where the relevant entity (manufacturer or authorised representative) is registered: • street/road; • number/house/floor; • postal code; • city; • state/region; and • country. - The information regarding street/road and number/house/floor may be omitted if a postal code dedicated to the manufacturer (corporate postal code) or authorized representative is used which fully replaces the indication of street/road and number/house/floor, and is not a PO box numbe."	Available Available Available Available • pass • pass • pass • pass • pass • pass	pass pass pass pass
§ 5.2 § 5.2.1	Specific requirements Applicability These specific requirements shall be applicable to all devices to the extent that they are applicable to the specific device type concerned and to the means of provision of the relevant information. For example, the requirement to allow for a "use by" date is not applicable to devices that do not bear a "use by" date.		n.a.
§ 5.2.2	Accessibility - The information presented with a device shall be accessible to intended users taking into account their age, education, knowledge and training. - When appropriate, a specific means of provision may be restricted to users to whom it is particularly applicabl	present	pass n.a.
§ 5.2.3	Legibility Information intended for visual recognition shall be easily legible when viewed using normal vision, corrected if necessary, taking into account the specific size and conditions of use of the particular device.	legible	pass
§ 5.2.4	Availability Information shall be available as long as reasonably necessary, taking the lifetime of the device into consideration.	Available	pass

§ 5.2.5	Security - As far as practicably possible, the medium of information provision shall be protected from corruption, degradation and deliberate change by those other than the manufacturer, whether malicious or not. - If the user can readily identify faulty information, for example by virtue of damaged labels, advice on the action to take shall be provided. - Where the damage to information is not readily apparent and/or the consequences of damage are not obvious, guidance shall be provided on how to maintain the security of the information and limit any adverse consequences.		pass pass n.a.
§ 5.2.6	Changes to information provided Any changes to information provided for existing users shall be clearly communicated if they are important for patient safety.		pass
§ 6	Documentation Documentation relating to information provided shall be maintained in the technical documentation(s) relating to the device(s) that are the subject of the information. This may take the form of a specific section holding all the documentation or, alternatively, references to parts of a larger document where the information may be found, such as a quality manual.	Information available	pass
	ISO 7176-15:1996		
§ 5	Requirements for disclosure of test information in manufacturer's specification sheets		
	The specification sheet shall contain the following: a. the model designation and/or any other information that will uniquely identify the wheelchair model; b the mass of the test dummy used in the test; c either: the performance values listed in annex A, in the order and using the wording shown:, (if applicable, with min and max values) 1. Overall length with leg rest, mm) 2. Overall width, (mm) 3. Folded length, (mm) 4. Folded width, (mm) 5. Folded height, (mm) 6. Total mass, (kg) 7. Mass of the heaviest part, (kg) 8. Static stability downhill, (°) 9. Static stability uphill, (°) 10. Static stability sideways, (°) 11. Energy consumption (km) 12. Dynamic stability uphill, (°) 13. Obstacle climbing, (mm) 14. Maximum speed forward, (km/h) 15. Minimum braking distance from max. speed, (mm) 16. Seat plane angle, (°) 17. Effective seat depth, (mm) 18. Effective seat width, (mm) 19. Seat surface height at front edge, (mm) 20. Backrest angle, (°) 21. Backrest height, (mm) 22. Footrest to seat distance, (mm) 23. Leg to seat surface angle, (°) 24. Armrest to seat distance, (mm)		a pass b pass c pass 1. pass 2. pass 3. pass 4. pass 5. pass 6. pass 7. pass 8. pass 9. pass 10. pass 11. pass 12. pass 13. pass 14. pass 15. pass 16. pass 17. pass 18. pass 19. pass 20. pass 21. pass 22. pass 23. pass 24. pass 25. pass

	25. Front location of armrest structure, (mm)			
	26. Handrim diameter, (mm) 27. Horizontal location of axle, (mm) 28. Minimum turning radius mm 29. The wheelchair conforms to the following standards: a. requirements and test methods for static, impact and fatigue strengths (ISO 7176-8) b. power and control systems for electric wheelchairs - requirements and test methods (ISO 7176-14) c. climatic test in accordance with ISO 7176-9 d. requirements for resistance to ignition in accordance with ISO 7176-16. if the part of ISO 7176 specifies a method of disclosure, that method shall have precedence d) maximum occupant mass			26. pass 27. pass 28. pass 29. pass d pass
§ 7	Documentation			
§ 7.1	General The following information shall be available in the official languages of countries in which the wheelchair is marketed.* a) The specification sheets (see clause 5), b) a statement as to which features and options are included in specific models of wheelchairs; c) a description of the intended use, (for example, maximum mass of the user, or indoor/outdoor use); d) either: i) details of the warranty, or ii) if no warranty is provided, a statement to that effect; e) information on how to get repairs and service. f) information as to whether a service manual is available., and g) an user manual.		 Information available Information available Information available Information available Information available Information available information available	 pass pass pass pass pass pass pass
§ 7.2 § 7.2.1 § 7.2.2	User manual At least one copy of the user manual shall be supplied with each wheelchair. When illustrations show components that are referred to in the text of the user manual, these components shall be numbered or named for positive identification. Illustrations shall be numbered or named for positive identification.		 Information available Information available	 pass pass
7.3	Contents of user manual			
	User manuals shall contain the following information: a) details of the warranty; b) general characteristics as follows: i) description of the wheelchair type; ii) description of the intended user including maximum occupant mass;		 In manual In manual	 Information available Information available	 a pass b pass

	iii) the environment in which the wheelchair is intended to be used; iv) if pneumatic tyres are fitted, the recommended inflation pressure; c) if a wheelchair is marketed for user-assembly, the following information: i) a list of components, ii) information about any tools or equipment for assembler, iii) instructions on how to inspect for missing or damaged parts, iv) instructions for assembling, installing and removing any parts (manufacturer), v) instructions on how to prepare the wheelchair for storage, shipment or travel, d) instructions for operation of the wheelchair as follows. i) complete operating instructions for safe use including: - instructions for operating the wheelchair on surfaces likely to be encountered by the user, - instructions for transfer of the user to and from the wheelchair, - illustrations to clarify these instructions; ii) any common misuse of the wheelchair known by the manufacturer that might lead to personal injury or damage to the wheelchair; e) maintenance instructions accompanied by annotated illustrations, and the following information: i) details of any maintenance, including: - any service, maintenance; - information about needed to repair and service the wheelchair; - frequency of maintenance; - a list of materials necessary; - identification of circumstances in which an operation should be undertaken by the manufacturer, distributor or service agent, ii) instructions on methods of cleaning, iii) for parts that the manufacturer intends to be readily replaced, the following: - ordering information, - instructions for access removal,	In manual In manual In manual	Information available Information available	c pass d pass e pass

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	- replacement and testing, and - annotated illustrations of the parts; iv) information on how to perform potentially hazardous maintenance operations; f) instructions for carrying out performance checks; g) description of wheelchair repair procedures as follows: i) identification of parts that are intended to be repaired by the user, ii) identification of parts that have to be serviced by the manufacturer or an authorized service facility in order to maintain warranties and serviceability, iii) identification of any parts that can be removed and sent to the manufacturer/ distributor or other party for repair, iv) identification of circumstances in which the manufacturer, distributor or service agent should undertake the repair, v) a list of authorized service facilities, If this information is not known, a clearly marked space for this information to be added by the supplier should be provided. vi) information on whether or not any replacement units are available, vii) packing and shipping instructions when necessary.	In manual In manual	Information available Information available	f pass g pass
§ 8	Permanent labelling			
§ 8.1	The following shall be marked in a permanent manner on each wheelchair:			
	a) the name and address of the manufacturer of the wheelchair; b) the model designation and serial number of the wheelchair; c) the year of manufacture; d) any driving restrictions; e) recommended maximum mass of the user.	Marked Marked Marked - Marked		a pass b pass c pass d pass e pass
§ 8.2	Tyres shall be marked with the size of the tyre.			pass

Remark: n.a. = not applicable

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End of report