Test report

Test report relating to an electrically powered scooter according to the European standard EN 12184:2014, concerning the product with trade mark: Mini Crosser, type: X1's & X2's, version: 3W, 4W, HD, 10 km/h & 15 km/h, manufactured by Medema Denmark A/S.

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Contents

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), identification

Subject	Specification/value
Sample number	89211946-01
Manufacturer	Medema Denmark A/S
Trade mark	Mini Crosser
Type	X1
Version	3W
Serial number	Proto 04
Max. user mass	175 kg
Dummy mass	175 kg
Trade mark and type of motor(s)	Mini Crosser
Trade mark and type of controller	Curtis Wright S-200
Maximum speed	10 km/h
Class according to EN 12184 § 5	C (outdoor)
Propulsion	rear wheel drive
Trade mark and type of front tyre	Trade mark: Mini Crosser, type: Radial Tube 13x5.00-6
Trade mark and type of rear tyre	Trade mark: Mini Crosser, type: Radial Tube 13x5.00-6
Trade mark and type of battery	Trade mark: Haze, type: 12V, 88Ah
Trade mark and type of battery charger	Trade mark: Medico, type: 24V, 10A

Subject	Specification/value
Sample number	89211946-03
Manufacturer	Medema Denmark A/S
Trade mark	Mini Crosser
Type	X1
Version	4W
Serial number	Proto 02
Max. user mass	175 kg
Dummy mass	175 kg
Trade mark and type of motor(s)	Mini Crosser
Trade mark and type of controller	Curtis Wright S-200
Maximum speed	10 km/h
Class according to EN 12184 § 5	C (outdoor)
Propulsion	rear wheel drive
Trade mark and type of front tyre	Trade mark: Mini Crosser, type: Radial Tube 13x5.00-6
Trade mark and type of rear tyre	Trade mark: Mini Crosser, type: Radial Tube 13x5.00-6
Trade mark and type of battery	Trade mark: Haze, type: 12V, 88Ah
Trade mark and type of battery charger	Trade mark: Medico, type: 24V, 10A

Subject	Specification/value
Sample number	89211946-05
Manufacturer	Medema Denmark A/S
Trade mark	Mini Crosser
Type	X1
Version	4W HD
Serial number	Proto 01
Max. user mass	250 kg
Dummy mass	250 kg
Trade mark and type of motor(s)	Mini Crosser
Trade mark and type of controller	Curtis Wright S-200
Maximum speed	10 km/h
Class according to EN 12184 § 5	C (outdoor)
Propulsion	rear wheel drive
Trade mark and type of front tyre	Trade mark: Mini Crosser, type: Radial Tube 13x5.00-6
Trade mark and type of rear tyre	Trade mark: Mini Crosser, type: Radial Tube 13x5.00-6
Trade mark and type of battery	Trade mark: Haze, type: 12V, 88Ah
Trade mark and type of battery charger	Trade mark: Medico, type: 24V, 10A

Subject	Specification/value
Sample number	89211946-02
Manufacturer	Medema Denmark A/S
Trade mark	Mini Crosser
Type	X1
Version	3W
Serial number	Proto 05
Max. user mass	175 kg
Dummy mass	175 kg
Trade mark and type of motor(s)	Mini Crosser
Trade mark and type of controller	Curtis Wright S-200
Maximum speed	15 km/h
Class according to EN 12184 § 5	C (outdoor)
Propulsion	rear wheel drive
Trade mark and type of front tyre	Trade mark: Mini Crosser, type: Radial Tube 13x5.00-6
Trade mark and type of rear tyre	Trade mark: Mini Crosser, type: Radial Tube 13x5.00-6
Trade mark and type of battery	Trade mark: Haze, type: 12V, 88Ah
Trade mark and type of battery charger	Trade mark: Medico, type: 24V, 10A

Subject	Specification/value
Sample number	89211946-04
Manufacturer	Medema Denmark A/S
Trade mark	Mini Crosser
Type	X1
Version	4W
Serial number	Proto 03
Max. user mass	175 kg
Dummy mass	175 kg
Trade mark and type of motor(s)	Mini Crosser
Trade mark and type of controller	Curtis Wright S-200
Maximum speed	15 km/h
Class according to EN 12184 § 5	C (outdoor)
Propulsion	rear wheel drive
Trade mark and type of front tyre	Trade mark: Mini Crosser, type: Radial Tube 13x5.00-6
Trade mark and type of rear tyre	Trade mark: Mini Crosser, type: Radial Tube 13x5.00-6
Trade mark and type of battery	Trade mark: Haze, type: 12V, 88Ah
Trade mark and type of battery charger	Trade mark: Medico, type: 24V, 10A

For pictures is referred to Appendix A.

1.3 Sampling procedure

TÜV Rheinland B.V. has had no influence on the selection of the sample.
The sample was test-worthy and was received on 31 October 2017 from the manufacturer.

1.4 Application

The request for testing was submitted by the manufacturer on 22 June 2017.

1.5 Method of testing

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

1.6 Used test equipment

Measuring instrument	Identification number
Amp-hour meter	A00519
Digital multi-meter	A00518
Noise meter	A01678
Mass 25 kg	A00531

Measuring instrument	Identification number
Back plate *	A01682
Buttock plate *	A01681
Feet plate *	A01680
ISO dummy **	A016xx
Test fixture dummy	A01679
Handheld tachometer	A00527
Angle plate (1)	A00512
Angle plate (2)	A00513
ISO double drum	A00526
High-pressure pump	A00551
IEC 60601-1 test finger	A00495
Calibration mass 25 kg	A00533
Small slope	A00505
Dynamometer push/pull impact	A00500
Laptop PC	A00534
Hygrometer	A00522
Measuring wheel	A00523
Pendulum 10 kg	A00502
Pendulum 25 kg	A00503
Power supply	A00515
Power supply	A00516
Measuring tape 5 m	A00535
Steel ruler 500 mm	A00554
Static impact set-up	A00504
Floor plate, fall test	A00536
Footrest height setting-up block 50	A00507
Weighing platform	A00506
Climatic chamber	A01878

1.7 Put out to contract

No tests were performed at third parties.

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.

1.9 Accreditation

TÜV Rheinland Nederland B.V. has been accredited by the Dutch Accreditation Council (RvA) as ISO 17025 Test Laboratory (nr. L 484) and product certification body (nr. C 078).

The reported tests were performed under ISO 17065 accreditation, unless otherwise specified as 'not under Accreditation'.

For an overview of all TÜV Rheinland Nederland B.V. accreditations, notifications and designations, is referred to our website www.tuv.com/nl. The relevant declarations can be found under the download link.

2 Summary of test results

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

Par.	Subject	Result (pass/fail/n.a.)
6	General requirements	pass
8	Performance requirements	pass
9	Component properties	pass
10	Propulsion and braking	pass
11	Operations	pass
12	Electrical systems	pass
13	Information supplied by the manufacturer	pass

3 Detailed test results

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
EN 12184 6	**General requirements**		
	Must conform to the mentioned requirements of EN 12182		
1	Intended performance and technical documentation (EN 12182, 4.2)	conforms Copied [13)]	pass
	Confirmation of sufficient strength and durability must be confirmed	conforms Copied [13)]	pass
	Intended performance described in technical documentation, if appropriate	conforms Copied [13)]	pass
	References described in technical documentation, if appropriate	conforms Copied [13)]	pass
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	conforms Copied [13)]	pass
3	Single use fasteners (EN 12182, 4.5)		
	If intended that it can be dismantled: no single use fasteners used	not applicable Copied [13)]	n.a.
4	Biocompatibility and toxity (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:	conforms Copied [13)]	pass
	The assessment shall take into account the intended use and contact by those involved in user care or transportation and storage of the product.	conforms Copied [13)]	pass
	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	conforms Copied [13)]	pass
5	Contaminants and residues (EN 12182, requirement 5.4)		
	Substances which may leak from an aid (e.g. oil, grease and acid) shall either:	not applicable	n.a.
	be assessed for biocompatibility conform guidance in EN ISO 10993-1 OR	not applicable	n.a.
	provided with protection against hazardous substance(s)	not applicable	n.a.
6	Infection and microbiological contamination (EN 12182, 5.5)	conforms	pass

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
	Cleaning and disinfection If intended to be cleaned: methods and materials in product-info. If intended to be disinfected: methods and materials in product-info.	 In product info not applicable	pass
	Animal tissue	not applicable	n.a.
7	Overflow, spillage, leakage and ingress of liquids		
	Overflow (EN 12182, 9.1): Overflow may not cause safety hazard(s).	conforms	pass
	Spillage (EN 12182, 9.2): Spillage may not cause safety hazard(s).	conforms	pass
	Leakage (EN 12182, 9.3): Leakage may not cause safety hazard(s).	conforms	pass
	Ingress of liquids (EN 12182, 9.4): Ingress of liquids may not cause safety hazard(s).	conforms	pass
8	Safety of moving parts (EN 12182, 12.1)		
	Moving parts that can cause an unintended safety hazard shall either:	conforms Copied [13)]	pass
	be provided with guards (removable with the use of tools only) OR have gaps which comply 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 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	conforms Copied [13)]	pass
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:		
	The risk of entrapment in V-shaped openings shall be assessed by the manufacturer.	conforms Copied [13)]	pass

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
	have a safe distance which complies with the applicable requirements for adults:		
	Finger traps: ≤ 8 mm or ≥ 25 mm	conforms	pass
	Foot traps: ≤ 35 mm or ≥ 100 mm	conforms	pass
	Head traps: ≤ 120 mm or ≥ 250 mm	not applicable	not applicable
	Genitalia traps: ≤ 8 mm or ≥ 75 mm	conforms	pass
	must have, if a hazardous situation can occur, a warning and instructions on safe use of the aid included in the manufacturer's instructions.	conforms Copied [13)]	pass
10	Folding and adjustment mechanisms shall either: (EN 12182, 14.3)		
	Be provided with means to protect the user from trap and or squeeze hazards OR	conforms Copied [13)]	pass
	have gaps which comply with the applicable requirements for adults:		
	Finger traps: ≤ 8 mm or ≥ 25 mm	conforms	pass
	Foot traps: ≤ 35 mm or ≥ 120 mm	conforms	pass
	Head traps ≤ 120 mm or ≥ 300 mm	conforms	pass
	Genitalia traps: ≤ 8 mm or ≥ 75 mm	conforms	pass
	OR	Copied [13)]	
	have a warning and instructions on how to operate the aid safely in the manufacturer's instructions (if hazardous situations can occur only)	conforms Copied [13)]	pass
11	Surfaces, corners and edges (EN 12182, 18)		
	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	conforms Copied [13)]	pass
	If not required for the intended function, aids shall not have (unprotected) projections	conforms Copied [13)]	pass
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 shall conform to the requirements of EN ISO 14155-1 and EN ISO 14155-2.	conforms	pass
13	Ergonomic principles (EN 12182, 23)	Copied [13)]	
	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.	conforms	pass
	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.	conforms	pass

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
	Grips, handles and pedals shall suit the functional anatomy of the user, according to the intended use and meet with the following requirements:	conforms	pass
a)	the distance between any handle (part intended to be grabbed) requiring an operating force of more than 10 N and any construction part of the assistive product shall not be less than 35 mm	conforms	pass
b)	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	not applicable	n.a.
c)	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	conforms	pass
d)	for assistive products operated from a standing position, pedals shall be placed not more than 300 mm above the surface of the floor	not applicable	n.a.
e)	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	not applicable	n.a.
f)	handles for pushing and/or pulling shall be placed at a minimum height of 900 mm	not applicable	n.a.
14	Risk analysis (EN 12182, 4.1) According to EN-ISO 14971	conforms	pass
EN 12184 **8**	**Wheelchair performance**		
8.1	**Performance of driving characteristics**		
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. Type class: C (outdoor) For detailed results is referred to Appendix B.	conforms	pass
8.1.2	Ability to climb rated slope		
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.	conforms Copied [13)]	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.	conforms Copied [13)]	pass
8.1.4	Maximum downhill speed.		

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**		**Value of the test**	**pass / fail / n.a**
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.		does not exceed 125% Copied [13)]	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.		conforms (Remark)	pass
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.		conforms	pass
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.		15° Copied [13)]	pass
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.		10,6 km/h forward 6,6 km/h reverse Copied [13)]	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.		53 km Copied [13)]	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. Details:	Must comply with all requirements: - static strength tests - impact strength tests - fatigue tests	 conforms conforms conforms Copied [16)]	pass
	8.4, Arm rests: downward	used load 950 N	conforms	
	8.5, Foot rests: downward	used load 1230 N	conforms	
	8.6, Tipping levers	used load 1000 N	conforms	
	8.7, Handgrips		not applicable	

Sample nr. Req. nr.	89211946-01, -02, -03, -04, -05 & -06 Description of the requirement		Value of the test	pass / fail / n.a
	8.8, Arm rests: upward		not applicable	
	8.9, Foot rests: upward		not applicable	
	8.10, Push handles, upward		not applicable	
	9.3, Back rest impact	used: pendulum (30°)	conforms	
	9.4, Handrim impact		not applicable	
	9.5, Castors impact		not applicable	
	9.6, Foot rests impact		not applicable	
	9.7, Front structure		conforms	
	10.4, Double drum test	200,000 cycles	conforms	
	10.5, drop test	6,666 cycles	conforms	
8.3	**Wheelchairs for use as seats in motor vehicles**			
	If intended use as seat in a motor vehicle by an occupant of a mass not less than 22 kg or greater shall conform to the performance requirements of ISO 7176-19:2008, with modifications to clause 4.1.2, 5.2.1 a) and 5.2.2 e) of ISO 7176-19:2008		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.			
ISO 7176-9, 8.2	Cold operating conditions, not less than 3 hours at -25 +2/-5 °C, functional check within 5 min of completion of the test		conforms Copied [16)]	pass
ISO 7176-9, 8.3	Hot operating conditions, not less than 3 hours at 50 +5/-2 °C, functional check within 5 min of completion of the test		conforms Copied [16)]	pass
ISO 7176-9, 8.4	Cold storage conditions, not less than 5 hours at -40 +/-5 °C, functional check after 1 hour and replacing of the removed batteries		conforms Copied [16)]	pass
ISO 7176-9, 8.5	Hot storage conditions, not less than 5 hours at 65 +/-5 °C, functional check after 1 hour		conforms Copied [16)]	pass
ISO 7176-9, 8.6	Protection against ingress of liquids, water spray test specified in 5.10 of IEC 60529, water sprayed from beneath		conforms Copied [16)]	pass
EN 12184 9	**Component properties**			
9.1	**Foot supports, leg support assemblies and arm supports**			
9.1.1	Foot supports shall have means for positioning the user's feet at the required height		conforms Copied [16)]	pass
9.1.1	Foot supports shall have means for preventing the user's feet from sliding backwards		not applicable	n.a.

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
a)	Incorporate a means to locate it securely in any intended operating position	not applicable	n.a.
b)	be adjustable in increments not exceeding 25 mm	not applicable	n.a.
c)	be accessible and operable: - by the occupant/assistant or both - in accordance with the manufacturer's intended use of the wheelchair.	not applicable	n.a.
d)	be within the reach space shown in Figure 1, and	not applicable	n.a.
e)	be operable without the use of tools The ability to make adjustments without the use of tools is not required.	not applicable	n.a.
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	not applicable	n.a.
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.	not applicable	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.	not applicable Copied [16)]	n.a.
9.3	**Pneumatic tyres**	conforms	pass
	(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	conforms Copied [16)]	pass
9.4	**Anterior pelvic support**		
	Shall have provision for an anterior pelvic to be fitted Shall be available as option And can be used with that provision	conforms	pass
9.5	**Resistance to ignition**		

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
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	conforms	pass
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	conforms	pass
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	conforms	pass
9.5.4	Power and control systems Either of the following options a) or b) shall apply.		
9.5.4 a)	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.	conforms Copied [13)]	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.	conforms Copied [13)]	pass
EN 12184 10	**Propulsion and braking systems**		
10.1	**Means for operating brakes**		
10.1.1 a)	Means for operating brakes shall:		
1)	be accessible and operable by the occupant or an assistant or both in accordance with the manufacturer's intended use of the wheelchair;	conforms Copied [16)]	pass
2)	be within the reach space shown in Figure 1, if the wheelchair is intended to be operated by the occupant;	conforms Copied [16)]	pass
3)	be within the reach space shown in Figure 3, if the wheelchair is intended to be operated solely by an assistant;	conforms Copied [16)]	pass
4)	have operating forces for engaging and disengaging as stated in Table 1 when tested in accordance with 10.1.2:	Copied [16)]	pass
	single finger 5 N		n.a.
	more than 1 finger 13,5 N	5,3 N	pass
	whole hand 60 N		n.a.

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
	hand + arm 60 N		n.a.
	foot, pushing 100 N		n.a.
	foot, pulling 60 N		n.a.
10.1.1 b)	If one of more braking levers are fitted, used on bicycles/ and mopeds:		
1)	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;		n.a.
2)	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;	36 N Copied [16)]	pass
3)	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).	97 mm Copied [16)]	pass
10.1 (sub c)	Means for releasing parking brakes shall be protected against activation caused by accidental contact.	conforms Copied [16)]	pass
10.2	**Braking functions** For test results is referred to Appendix B.		
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.	conforms Copied [16)]	pass
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.	conforms Copied [16)]	pass
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).	conforms Copied [16)]	pass
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)	conforms Copied [16)]	pass
e)	Parking brakes shall meet the parking brake effectiveness requirement in Table 1 when tested in accordance with 10.2.2.2.	conforms Copied [16)]	pass
f)	Parking brakes shall be operable when there is no power from the battery supplying the drive system,	conforms Copied [16)]	pass
g)	Parking brakes shall be operable when the wheelchair is in freewheel mode	conforms Copied [16)]	pass
h)	If they are subject to wear, parking brakes shall have provision for adjustment and/or replacement as specified by the manufacturer.	conforms Copied [16)]	pass

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
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.	conforms Copied 16)	pass
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.	conforms Copied 16)	pass
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.	conforms Copied 16)	pass
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	conforms Copied 16)	pass
	- be within the reach space shown in Figure 1, if the wheelchair is intended to be operated by the occupant	conforms Copied 16)	n.a.
	- be within the reach space shown in Figure 3, if the wheelchair is intended to be operated solely by an assistant	conforms Copied 16)	pass
	- have operating forces for engaging and disengaging that do not exceed those stated in Table 1	conforms Copied 16)	pass
	- be operable without detaching any parts	conforms Copied 16)	pass
	- not depend on the battery power supplying the motor drive system	conforms Copied 16)	pass
	- have two defined positions including clear indication of freewheel mode and drive mode	conforms Copied 16)	pass
	- prevent use of the wheelchair's drive system, if the freewheel device is activated	conforms Copied 16)	pass
	(A battery independent from the motor drive battery may be used to supply energy to enable freewheel mode)		
EN 12184 11	**Operations**		
11.1	**Operations intended to be carried out by the occupant and/or assistant**		
	The wheelchair shall be designed to facilitate ease of operation by user/attendant as specified the manufacturer instructions	conforms Copied 16)	pass
11.2	**Controls intended to be operated by the occupant**		

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
	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:	Copied [16)]	
	on/off switch or key	conforms	pass
	speed regulator	conforms	pass
	speed pre-setting	conforms	pass
	running brake	conforms	pass
	parking brake	conforms	pass
	audible warning device	conforms	pass
	direction indicator	conforms	pass
	direction switch	conforms	pass
	control device	conforms	pass
	manual steering controls	conforms	pass
	lighting controls	conforms	pass
	seating adjustments	conforms	pass
	detachable components, including removable arm supports, lower leg support assemblies, etc., to facilitate safe transfers into and out of the wheelchair	conforms	pass
	steering controls	conforms	pass
	freewheel device	conforms	pass
11.3	**Controls operated by an assistant**		
	Controls intended to be operated by an assistant shall be within the assistant reach space shown in figure 3. Examples include: — brakes, — control devices, — push handles, and — electrical ancillary equipment.	not applicable Copied [16)]	n.a.
11.4	**Assistant control unit, push handles and handgrips**		
11.4.1	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, - 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 - there shall be a means to support the assistant's hand or hands used to operate the control device.	not applicable	n.a.

Sample nr. Req. nr.	89211946-01, -02, -03, -04, -05 & -06 Description of the requirement	Value of the test	pass / fail / n.a
	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.	not applicable	n.a.
	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.	not applicable	n.a.
	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.	not applicable	n.a.
11.5	**Operating forces**		
11.5.1	All controls, except for means to operate brakes, shall have operating forces for engaging and releasing that do not exceed those stated in Table 1 when tested in accordance with 11.5.2.	Copied [13)]	pass
11.6	**Seating adjustments for tilt and recline systems**		
11.6.1	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	conforms Copied [13)]	pass
	Controls intended to be operated by the occupant while seated shall be within the users reach.	conforms Copied [13)]	pass
EN 12184 12	**Electrical systems**		
12.1	**General requirements**		
	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	conforms Copied [16)] conforms Copied [16)] not applicable	pass
12.2	**Circuit protection**		

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
	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. Circuit protection devices that carry the total current of the battery set may be used.	conforms Copied 16) conforms Copied 16) conforms Copied 16)	pass
12.3	**Battery chargers**		
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	conforms Copied 16)	pass
b)	Battery chargers shall have the capability of charging batteries discharged to 70 % of their nominal voltage;	conforms Copied 16)	pass
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;	conforms Copied 16)	pass
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.	not applicable Copied 16)	pass
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.	conforms Copied 16)	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.	conforms Copied 16)	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.	conforms Copied 16) conforms Copied 16) conforms Copied 16)	pass

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
	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.	conforms conforms conforms conforms conforms	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.	conforms Copied [16)]	pass
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.	conforms Copied [16)]	pass
12.9	**Software**		
	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.	conforms Copied [16)]	pass
EN 12184 13	**Information supplied by the manufacturer**		
13.1	**General**		
	Each wheelchair shall be provided with documentation and labelling that conform to the requirements in EN 12182 (including EN 1041) and ISO 7176-15:1996.		
	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.	conforms Copied [13)]	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.	conforms Copied [13)]	pass
13.2	**Pre-sale information**		

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
	In addition to the requirements of 13.1, pre-sale information shall include the following	Copied [13)]	
a)	information on how to obtain the user information in a format appropriate for use by visually impaired people	available	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	available	pass
c)	the intended operator (occupant, assistant or both)	available	pass
d)	description of the intended use and the intended environment	available	pass
e)	the type class of the wheelchair: Class A, Class B or Class C	available	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	available	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	not applicable	n.a.
h)	the minimum width of corridor in which the wheelchair can be turned to face the opposite direction	available	pass
i)	the rated slope, expressed in degrees	available	pass
j)	the standard options that are available for the wheelchair	available	pass
k)	the type(s) of tyres that can be used on the wheelchair	available	pass
l)	operator adjustments	available	pass
m)	if the wheelchair can be dismantled or has any removable parts, the mass of the heaviest part	available	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	not applicable	n.a.
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)	available	pass
p)	information on whether the unoccupied wheelchair is suitable for land and/or air transport	available	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 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	available	pass

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
r)	the maximum height of kerb which the wheelchair can descend safely	available	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	available	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	Copied [13)]	
a)	the unique identification number of the wheelchair or information on the location of the unique identification number on the wheelchair	available	pass
b)	any adjustment or settings required before the wheelchair can be used and warnings of how adjustments or settings affect stability	available	pass
c)	where applicable, information on any adjustments that can be made and the competency required to carry out these adjustments	available	pass
d)	instructions on operation of all controls, including brakes	available	pass
e)	instructions on how to engage and disengage the drive system	available	pass
f)	the wheelchair manufacturer's recommended tyre pressure(s), expressed in kPa, bar or PSI	available	pass
g)	instructions for dealing with tyre punctures, where pneumatic tyres are fitted	available	pass
h)	the battery type and nominal voltage	available	pass
i)	instructions for battery maintenance	available	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)	available	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	available	pass
l)	instructions on whether and how the wheelchair can be folded to assist in storage or transport	available	pass
m)	instructions on dismantling and re-assembly of the wheelchair or any removable parts	available	pass
n)	instructions regarding transport of the wheelchair when it is unoccupied (e.g. in a car or aeroplane)	available	pass
o)	the masses of parts of the wheelchair that are expected to be handled during dismantling, reassembly, or carrying	available	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	available	pass

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
q)	if the manufacturer specifies that the wheelchair is intended for use as a seat in a motor vehicle, the method of attaching wheelchair tiedown and occupant restraints, and recommendations about suitable tiedown and restraint systems	available	pass
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	not applicable	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	available	pass
t)	the positions of points intended to carry additional loads	not applicable	n.a.
u)	instructions for preparing the wheelchair for long-term storage (e.g. longer than four months) and for preparing it for use afterward	available	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.)	available	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)	available	pass
x)	a warning that the stopping distance on slopes can be significantly greater than on level ground	available	pass
y)	a warning that surface temperatures can increase when exposed to external sources of heat (e.g. sunlight)	available	pass
z)	a warning for trapping hazards (e.g. pinch points)	available	pass
aa)	a warning if driving characteristics can be adjusted outside the limits specified in Table 1 and Table 2	available	pass
bb)	a warning if the adjustments of seating or wheel positions can be set outside safe limits	available	pass
cc)	if the overall width or overall length of the wheelchair when it is ready for use exceed the applicable values recommended in A.1.1, a warning concerning access to emergency escape routes	available	pass
dd)	the level of resistance to ignition of materials and assemblies	available	pass
ee)	information on the recycling of used batteries and of the wheelchair	available	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)	not applicable	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	not applicable	n.a.
hh)	the expected service life of the wheelchair	available	pass
ii)	the name and address of the manufacturer	available	pass

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
jj)	the name and address of the authorised representative, where the manufacturer does not have a registered place of business in the European Union	available	pass
13.4	**Service information**	Copied [13)]	pass
	The service information shall contain all the pre-sale information, user information and instructions necessary for the maintenance, adjustment and repair of the wheelchair and for the replacement of parts	available	pass
13.5	**Labelling**		
	In addition to the requirements of 13.1, the manufacturer shall apply permanent labelling for the following:	Copied [13)]	
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	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)	available	pass
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 7176-15:1996	not applicable	n.a.
d)	for battery chargers that are not on-board chargers, information and connection details specified in Clause 9 of ISO 7176-14:1997	available	pass
e)	for Class A wheelchairs not intended for use outdoors, a warning to that effect	not applicable	n.a.
EN 12182 24	**Requirements for information supplied by the manufacturer according to EN 12182:2012**		
24.1	The information supplied by the manufacturer comprises the data in the instructions for use and the details on the label.		
	The information applied to, and supplied with, assistive products shall conform to EN 1041.	conforms	pass
	Assistive products covered by the scope of a specific standard shall also, in addition to EN 12182, conform to the requirements according to the clause dealing with information regarding electrical aspects of the product.	conforms	pass
	Any means of provision of information with assistive products shall take into account the intended users, the conditions of use and any issues specific to individual assistive product types that are necessary for the safe and effective use of the product.	conforms	pass
	Special attention shall be paid to the user information, particularly the instructions on operation and the design of labels and the design and presentation of warnings.	conforms	pass

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
	In addition, the manufacturer should provide the information in the instructions for use in three separate sections: pre-sale, user and service information as specified in 24.2.1, 24.2.2 and 24.2.3. These may be provided as separate printed documents or in other forms of media to meet the needs of individual users or their assistants.	conforms	pass
	If the manufacturer is not located in the European Community, the manufacturer is required to designate an 'EC authorised representative' established in the European Community. In such cases and to comply fully with the Essential Requirements of EU Directive 93/42/EEC on medical devices, the name and address of the authorised representative are required	not applicable	n.a.
24.2	**Instructions for use**		
24.2.1	**Pre-sale information** In addition to the requirements of 24.1, pre-sale information shall include the following:		
a)	information on how to obtain the user information in a format appropriate for use by people with visual, reading or cognitive disabilities	conforms	pass
b)	all information shall as far as possible be available in Pictogram	conforms	pass
c)	a description of the intended use and the intended environment	conforms	pass
d)	maintenance instructions, if applicable	conforms	pass
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	conforms	pass
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	not applicable	n.a.
g)	the overall dimensions (width, length and height) of the assistive product, expressed in millimetres, and its mass, expressed in kilograms, when it is ready for use and, if applicable, when it is folded or dismantled	conforms	pass
h)	the mass expressed in kilograms if the assistive product can be dismantled or has any removable parts that has a mass which is heavier than 10 kg;	conforms	pass
i)	the assistive product is supposed to be used in combination with other products, the manufacturer shall state to which products, and how this can be done in a safe way	conforms	pass
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	not applicable	n.a.

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
k)	a list of accessories, detachable parts and materials that the manufacturer has determined as being intended for use with the assistive product	conforms	pass
l)	if a programmable controller is fitted, information on the method of programming, the competence required to carry out the programming and the effects on performance	conforms	pass
m)	operator control adjustments	conforms	pass
n)	whether and how the assistive product can be folded or dismantled to assist in storage or transport	conforms	pass
o)	instructions regarding transport of the assistive product (e.g. in a car or aeroplane)	conforms	pass
p)	measured sound power level	conforms	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 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	conforms	pass
b)	the intended user	conforms	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	conforms	pass
d)	information on adjustment possibilities and the competence required to carry out these adjustments	conforms	pass
e)	instructions on operation of all controls	conforms	pass
f)	the battery type and nominal voltage	conforms	pass
g)	instructions for battery maintenance	conforms	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)	conforms	pass
i)	instructions on dismantling and re-assembly of the assistive product or any removable parts	conforms	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	conforms	pass
k)	a warning if surface temperatures can increase / decrease when exposed to external sources of heat or cold (e.g. sunlight, outdoor environment);	conforms	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.)	conforms	pass

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
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	conforms	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	conforms	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	conforms	pass
p)	the level of resistance to ignition of materials and assemblies	conforms	pass
q)	information on the recycling of used batteries and other parts of the assistive product	conforms	pass
r)	expected lifetime of the assistive product	conforms	pass
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.	conforms	pass
	The service information shall contain all the pre-sale information and the user information.	conforms	pass
	The service information shall be sufficiently detailed concerning preventive inspection, maintenance and calibration, including the frequency of such maintenance.	conforms	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.	conforms	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.	conforms	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	conforms	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	conforms	pass
	Symbols for use in the labelling of medical devices shall be in accordance with EN 980	conforms	pass
25	**Packaging**		
	The hazards that can be caused by inadequate protective packaging shall be assessed in the risk analysis (see 4.1).	not applicable	n.a.

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
	EN 1041, Information supplied by the manufacturer of medical devices		
EN 1041 **4.1**	General		
	Product information and labelling shall be part of risk management procedures.	conforms	pass
4.2	Units, symbols and colours		
	Units used shall be SI units as specified in ISO 1000 or any other legal units.	conforms	pass
	Symbols and safety-related identification colours shall be explained in the information supplied unless they are taken from harmonised standards	conforms	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”).	conforms	pass
	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”).	conforms	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.	conforms	pass
4.5	Device nomenclature		
4.5.1	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.	conforms	pass
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.	conforms	pass
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.	conforms	pass
5	Requirements for provision of information	Copied [13)]	

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
5.1	General		
5.1.1	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.	conforms	pass
	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.	conforms	pass
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 authorised representative.	conforms	pass
	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 Community, the label, or the outer packaging, or instructions for use shall contain, in addition, the name and address of the authorised representative.	conforms	pass
	For devices covered by the AIMDD, etc. etc.	not applicable	n.a.
	The address to be used shall be the same as the address of the manufacturer and/or the authorised 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.	conforms	pass
	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	conforms	pass
	- number/house/floor	conforms	pass
	- postal code	conforms	pass
	- city	conforms	pass
	- state/region	conforms	pass
	- country	conforms	pass

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
	The information regarding street/road and number/house/floor may be omitted if a postal code dedicated to the manufacturer (corporate postal code) or authorised representative is used which fully replaces the indication of street/road and number/house/floor, and is not a PO box number.	conforms	pass
5.2	Specific requirements		
5.2.1	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.	not applicable	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.	conforms	pass
	When appropriate, a specific means of provision may be restricted to users to whom it is particularly applicable.	conforms	pass
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.	conforms	pass
5.2.4	Availability		
	Information shall be available as long as reasonably necessary, taking the lifetime of the device into consideration.	conforms	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.	conforms	pass
	If the user can readily identify faulty information, for example by virtue of damaged labels, advice on the action to take shall be provided.	conforms	pass
	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.	conforms	pass
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.	conforms	pass
6	Documentation		

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
	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.	conforms	pass
	ISO 7176-15:1996	Copied [13)]	
ISO 7176-15	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	conforms	pass
	b. the mass of the test dummy used in the test	conforms	pass
	either: i) the performance values listed in annex A, in the order and using the wording shown, or ii) if the part of IS0 7176 specifies a method of disclosure, that method shall have precedence over i)	 conforms not applicable	 pass n.a.
	d. maximum occupant mass.	conforms	pass
i) Annex A	Overall length with leg rest, (mm)	conforms	pass
	Overall width, (mm)	conforms	pass
	Folded length, (mm)	not applicable	n.a.
	Folded width, (mm)	not applicable	n.a.
	Folded height, (mm)	not applicable	n.a.
	Total mass, (kg)	conforms	pass
	Mass of the heaviest part, (kg)	conforms	pass
	Static stability downhill, (°)	conforms	pass
	Static stability uphill, (°)	conforms	pass
	Static stability sideways, (°)	conforms	pass
	Energy consumption (km)	conforms	pass
	Dynamic stability uphill, (°)	conforms	pass
	Obstacle climbing, (mm)	conforms	pass
	Maximum speed forward, (km/h)	conforms	pass
	Minimum braking distance from max. speed, (mm)	conforms	pass
	Seat plane angle, (°)	conforms	pass
	Effective seat depth, (mm)	conforms	pass

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
	Effective seat width, (mm)	conforms	pass
	Seat surface height at front edge, (mm)	conforms	pass
	Backrest angle, (°)	conforms	pass
	Backrest height, (mm)	conforms	pass
	Footrest to seat distance, (mm)	conforms	pass
	Leg to seat surface angle, (°)	conforms	pass
	Armrest to seat distance, (mm)	conforms	pass
	Front location of armrest structure, (mm)	conforms	pass
	Handrim diameter, (mm)	not applicable	n.a.
	Horizontal location of axle, (mm)	not applicable	n.a.
	Minimum turning radius mm	conforms	pass
	The wheelchair conforms to the following standards: 1. requirements and test methods for static, impact and fatigue strengths (ISO 7176-8) 2. power and control systems for electric wheelchairs - requirements and test methods (ISO 7176-14) 3. climatic test in accordance with ISO 7176-9 4. requirements for resistance to ignition in accordance with ISO 7176-16.	 conforms conforms conforms not applicable	 pass pass pass n.a.
7	Documentation	Copied [13)]	
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)	conforms	pass
b)	a statement as to which features and options are included in specific models of wheelchairs	conforms	pass
c)	a description of the intended use, (for example, maximum mass of the user, or indoor/outdoor use)	conforms	pass
d)	Either:		
	i) details of the warranty, or	conforms	pass
	ii) if no warranty is provided, a statement to that effect	conforms	pass
e)	information on how to get repairs and service	conforms	pass
f)	information as to whether a service manual is available	conforms	pass
g)	an user manual	conforms	pass

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
7.2 7.2.1	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.	 conforms conforms	 pass pass
7.3	Contents of user manual	Copied [13)]	
	User manuals shall contain the following information:		
a)	details of the warranty;	conforms	pass
b)	general characteristics as follows:		
	i) description of the wheelchair type	conforms	pass
	ii) description of the intended user including maximum occupant mass	conforms	pass
	iii) the environment in which the wheelchair is intended to be used	conforms	pass
	iv) if pneumatic tyres are fitted, the recommended inflation pressure	conforms	pass
c)	if a wheelchair is marketed for user-assembly, the following information:		
	i) a list of components	conforms	pass
	ii) information about any tools or equipment for assembler	conforms	pass
	iii) instructions on how to inspect for missing or damaged parts	conforms	pass
	iv) instructions for assembling, installing and removing any parts (manufacturer)	conforms	pass
	v) instructions on how to prepare the wheelchair for storage, shipment or travel	conforms	pass
d)	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	conforms	pass
	- instructions for transfer of the user to and from the wheelchair	conforms	pass
	illustrations to clarify these instructions;	conforms	pass
	ii) any common misuse of the wheelchair known by the manufacturer that might lead to personal injury or damage to the wheelchair	conforms	pass
e)	maintenance instructions accompanied by annotated illustrations, and the following information: i) details of any maintenance, including:	 conforms	 pass
	- any service, maintenance	conforms	pass
	- information about needed to repair and service the wheelchair	conforms	pass

Sample nr. **Req. nr.**	89211946-01, -02, -03, -04, -05 & -06 **Description of the requirement**	**Value of the test**	**pass / fail / n.a**
	- frequency of maintenance	conforms	pass
	- a list of materials necessary	conforms	pass
	- identification of circumstances in which an operation should be undertaken by the manufacturer, distributor or service agent	conforms	pass
	ii) instructions on methods of cleaning	conforms	pass
	iii) for parts that the manufacturer intends to be readily replaced, the following	conforms	pass
	- ordering information	conforms	pass
	- instructions for access removal	conforms	pass
	- replacement and testing, and	conforms	pass
	- annotated illustrations of the parts	conforms	pass
	iv) information on how to perform potentially hazardous maintenance operations	conforms	pass
f)	instructions for carrying out performance checks	conforms	pass
g)	description of wheelchair repair procedures as follows:		
	i) identification of parts that are intended to be repaired by the user	conforms	pass
	ii) identification of parts that have to be serviced by the manufacturer or an authorized service facility in order to maintain warranties and serviceability	conforms	pass
	iii) identification of any parts that can be removed and sent to the manufacturer/ distributor or other party for repair	conforms	pass
	iv)identification of circumstances in which the manufacturer, distributor or service agent should undertake the repair	conforms	pass
	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.	conforms	pass
	vi) information on whether or not any replacement units are available	conforms	pass
	vii) packing and shipping instructions when necessary	conforms	pass
8	Permanent labelling	Copied [13)]	
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	conforms	pass
	b) the model designation and serial number of the wheelchair	conforms	pass
	c) the year of manufacture	conforms	pass
	d) any driving restrictions	conforms	pass
	e) recommended maximum mass of the user	conforms	pass
§ 8.2	Tyres shall be marked with the size of the tyre.	available	pass

4 Remarks on the test results

Req.nr.	Description of the requirement	Remark
		The results in this report are also applicable for the electrical seat with functions forward, reverse and incline.
8.1.5	Dynamic stability	The dynamic stability was tested without anti tipping devices.

5 Conclusion

The scooter, trade mark: Mini Crosser, types: X1's & X2's, version: 3W, 4W, HD, 10 km/h & 15 km/h meets the applicable requirements as stated in the European Standard EN 12184 [1] for a class C (outdoor) scooter.

The test results exclusively relate to the tested object.

Remark 1

The test results regarding the performance requirements strongly depend on how the driving characteristics were programmed in the driving module (power controller) during testing.

Remark 2

When and if changes are made in production method and/or equipment, assessment according to this standard shall be reconsidered and re-tests shall be performed when the changes can lead to different specifications of the product. The decision and responsibility lies at the manufacturer.

Remark 3

Some results have been copied from other TÜV Rheinland Nederland reports:

- Copied [1)]: Results have been copied from report 8920 3227
- Copied [2)]: Results have been copied from report 8920 3227.02
- Copied [3)]: Results have been copied from report 8920 3227.03
- Copied [4)]: Results have been copied from report 8920 3227.03-02
- Copied [5)]: Results have been copied from report 8920 3227.04
- Copied [6)]: Results have been copied from report 8920 3227.04-2
- Copied [7)]: Results have been copied from report 8920 5425
- Copied [8)]: Results have been copied from report 8920 5415.01
- Copied [9)]: Results have been copied from report 8920 5415.02
- Copied [10)]: Results have been copied from report 8920 5415.03
- Copied [11)]: Results have been copied from report 8920 5415.04
- Copied [12)]: Results have been copied from report 8920 5415.05
- Copied [13)]: Results have been copied from report 8920 6053.01
- Copied [14)]: Results have been copied from report 8920 6053.02
- Copied [15)]: Results have been copied from report 8920 6053.03
- Copied [16)]: Results have been copied from report 8921 1946-02

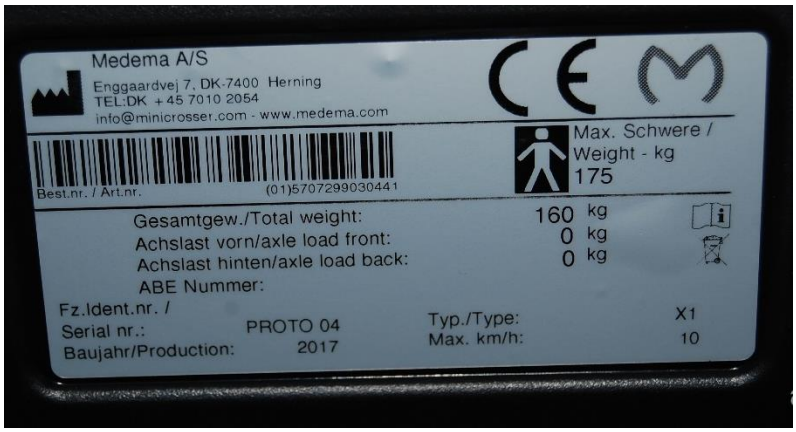
6 References

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

7 Signatures

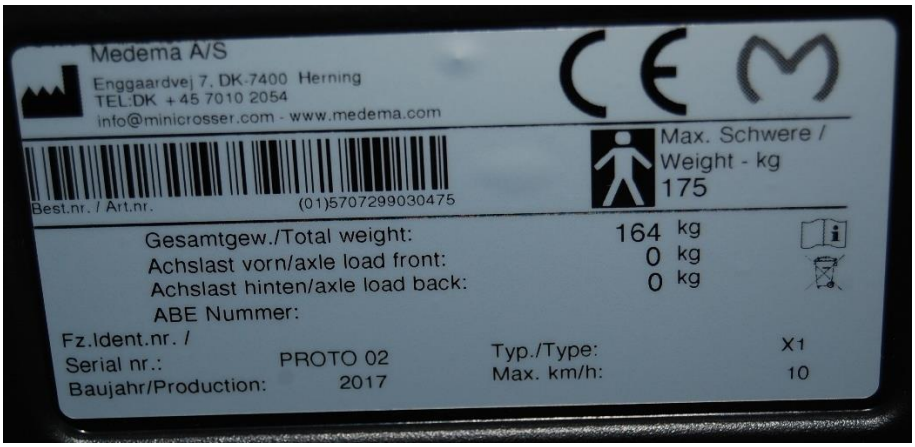
Author	**Signature**
Mr. M.J.H. Braun, B.E. Expert Medical Products	
Approved by	**Signature**
Mr. T.R. Cruijff Expert Medical Products	

Appendix A, Pictures of the tested product

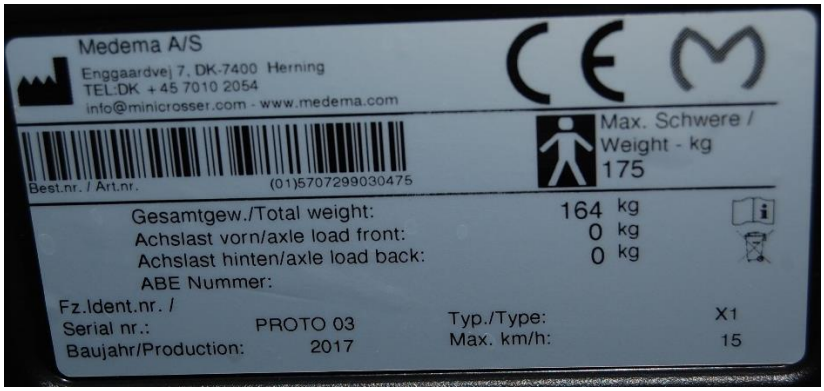


Sample 8921 1946-01

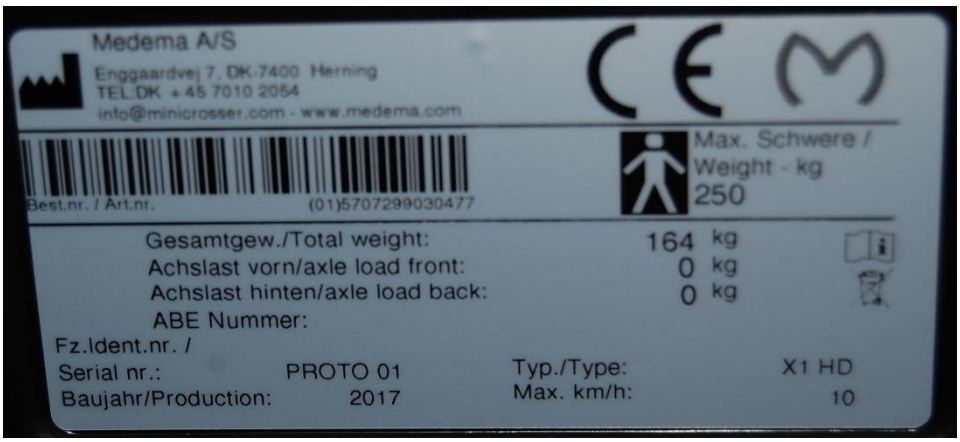
Sample 8921 1946-02



Sample 8921 1946-03



Sample 8921 1946-04



Sample 8921 1946-5

Picture(s) of the tested sample, trade mark: Mini Crosser, type: X1's & X2's, version: 3W, 4W, HD, 10 km/h & 15 km/h

Appendix B, Results of driving tests according to Table 1 and 2 of EN 12184 [1]

Requirements/results	Requirements for Class	Results when tested for Class C (outdoor)
TABLE 1		
Subject	**C**	
Rated slope	10	Score
Dynamic stability in º		
- Starting forwards uphill	10	2
- Stopping forwards uphill	10	3
- Stopping forwards downhill	10	3
- Stopping backwards downhill	10	2
- Turning on a slope	(1)	3
Static stability in º		
- All directions	15 (2)	>22,4°
Maximum operating force in N		
- Single finger operation	5	N.A.
- More than 1 finger operation	13,5	5,3
- Whole hand operation	60	36
- Combined hand/arm operation	60	N.A.
- Foot operation, pushing	100	N.A.
- Foot operation, pulling	60	N.A.
Park brake effectiveness in º Copied [13)]	15 (3)	>15°
Speed in km/h Copied [13)]		
- Forwards horizontal	15	10,6
- Reverse horizontal	(4)	6,6
Minimum obstacle climbing and descending ability in mm Copied [13)]	100	100
Minimum theoretical continious driving distance range in km Copied [13)]	35	53
TABLE 2		
Horizontal stopping distance (m) at Vmax. (km/h) Copied [13)]		Vmax: 10,3 km/h Distance: 1,6 m

(1) No tipping beyond balance point shall occur. Not applicable, except for X-joy.

(2) Minimum slope OR the rated slope claimed by the manufacturer if greater

(3) OR the rated slope claimed by the manufacturer if greater

(4) 70% of maximum forward speed of the wheelchair OR 5 km/h whichever is lower

This is the end of this report.