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# Test report

Test report relating to an electrically powered wheelchair according to the European standard EN 12184:2014, concerning the product with trade mark: Medema, type: MC1124, manufactured by Medema Denmark A/S.

| | |
|---|---|
| Report number | 89212829-01 |
| Date | 17 May 2018 |
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| Project number | 89212829 |
| Project name | Testing MC1124 according to EN12184 |
| Number of pages | 38 |

PRODUCTEN
RvA C 078

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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), identification

| Subject | Specification/value |
|---|---|
| Manufacturer | Medema Denmark A/S |
| Trade mark | Medema |
| Type | MC1124 |
| Serial number | 2017-12-005 |
| Max. user mass | 150 kg |
| Dummy mass | 150 kg |
| Trade mark and type of controller | Penny & Giles, S-drive |
| Maximum speed | 10 km/h |
| Class according to EN 12184 § 5 | B (indoor/outdoor) |
| Propulsion | mid wheel drive |
| Trade mark and type of front tyre | Trade mark: Primo, type: Powertrax (3.00x8) |
| Trade mark and type of rear tyre | Trade mark: Not visible, type: R170125A |
| Trade mark and type of battery | Trade mark: Move, type: MPX 55-12 |
| Trade mark and type of battery charger | Trade mark: J.K. Medico, type: CCC410S |

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 19 December 2017 from the manufacturer.

## 1.4 Application

The request for testing was submitted by the manufacturer on 18 December 2017.

## 1.5 Method of testing

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

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## 1.6 Used test equipment

| Measuring instrument | Identification number |
|---|---|
| Amp-hour meter | A00519 |
| Digital multi-meter | A00518 |
| Noise meter | A01678 |
| Mass 25 kg | A00531 |
| 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 |
| Small slope | A00505 |
| Dynamometer push/pull impact | A00500 |
| Laptop PC | A00534 |
| Luxmeter | A00555 |
| 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 |

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### 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, please visit our website www.tuv.com/nl. You can find the relevant declarations under the downlaod link.

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## 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 |

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## 3 Detailed test results

| **Sample nr.**<br><br>**Req. nr.** | 89212829-03<br><br>**Description of the requirement** | **Value of the test** | **pass / fail / n.a** |
|---|---|---|---|
| **EN 12184**<br>**6** | **General requirements** | | |
| | Must conform to the mentioned requirements of EN 12182 | | |
| 1 | Intended performance and technical documentation (EN 12182, 4.2) | | |
| | Confirmation of sufficient strength and durability must be confirmed | conforms | pass |
| | Intended performance described in technical documentation, if appropriate | conforms | pass |
| | References described in technical documentation, if appropriate | conforms | 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 | pass |
| 3 | Single use fasteners (EN 12182, 4.5) | | |
| | If intended that it can be dismantled: no single use fasteners used | conforms | pass |
| 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 | 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 | 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 | 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) | | |
| | Cleaning and disinfection<br>If intended to be cleaned: methods and materials in product-info.<br>If intended to be disinfected: methods and materials in product-info. | <br>In product info<br>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). | not applicable | n.a. |

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| **Sample nr.**<br><br>**Req. nr.** | 89212829-03<br><br>**Description of the requirement** | **Value of the test** | **pass / fail / n.a** |
|---|---|---|---|
| | Spillage (EN 12182, 9.2): Spillage may not cause safety hazard(s). | not applicable | n.a. |
| | Leakage (EN 12182, 9.3): Leakage may not cause safety hazard(s). | not applicable | n.a. |
| | 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: | | |
| | be provided with guards (removable with the use of tools only)<br>OR | conforms | pass |
| | have gaps which comply with the applicable requirements for adults: | conforms | |
| | Finger traps: ≤ 8 mm or ≥ 25 mm | >25 mm | pass |
| | Foot traps: ≤ 35 mm or ≥ 100 mm | | n.a. |
| | Head traps: ≤ 120 mm or ≥ 250 mm | | n.a. |
| | Genitalia traps: ≤ 8 mm or ≥ 75 mm | | n.a. |
| | 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)<br>OR | conforms | pass |
| | have a control device which stops movement immediately when not operated.<br>OR | not applicable | n.a. |
| | have a detecting device which stops movement automatically and immediately when a safety hazard occurs | not applicable | n.a. |
| 9 | Prevention of traps for parts of human body (EN 12182, 13)<br>Holes in and clearances between stationary parts (if accessible by user or attendant) shall either: | | |
| | V-shaped openings | | |
| | The risk of entrapment in V-shaped openings shall be assessed by the manufacturer. | assessed | pass |
| | have a safe distance which complies with the applicable requirements for adults: | conforms | pass |
| | Finger traps: ≤ 8 mm or ≥ 25 mm | ≥25 mm | pass |
| | Foot traps: ≤ 35 mm or ≥ 100 mm | | n.a. |
| | Head traps: ≤ 120 mm or ≥ 250 mm | | n.a. |
| | Genitalia traps: ≤ 8 mm or ≥ 75 mm | | n.a. |

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| **Sample nr.**<br><br>**Req. nr.** | 89212829-03<br><br>**Description of the requirement** | **Value of the test** | **pass / fail / n.a** |
|---|---|---|---|
| | must have, if a hazardous situation can occur, a warning and instructions on safe use of the aid included in the manufacturer's instructions. | not applicable | n.a. |
| 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<br>OR | conforms | pass |
| | have gaps which comply with the applicable requirements for adults: | | |
| | Finger traps: ≤ 8 mm or ≥ 25 mm | ≥25 mm | pass |
| | Foot traps: ≤ 35 mm or ≥ 120 mm | | n.a. |
| | Head traps ≤ 120 mm or ≥ 300 mm | | n.a. |
| | Genitalia traps: ≤ 8 mm or ≥ 75 mm | | n.a. |
| | OR | | |
| | have a warning and instructions on how to operate the aid safely in the manufacturer's instructions (if hazardous situations can occur only) | conforms | 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 | pass |
| | If not required for the intended function, aids shall not have (unprotected) projections | conforms | pass |
| 12 | Clinical evaluation (EN 12182, 4.3) | | |
| | A clinical evaluation shall be done for all assistive products.<br>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) | | |
| | 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.<br>The ergonomic principles set out in EN 614-1 shall apply to all involved persons. | conforms | pass |
| | 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 |

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| **Sample nr.**<br><br>**Req. nr.** | 89212829-03<br><br>**Description of the requirement** | **Value of the test** | **pass / fail / n.a** |
|---|---|---|---|
| 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 | conforms | pass |
| 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 | conforms | pass |
| f) | handles for pushing and/or pulling shall be placed at a minimum height of 900 mm | conforms | pass |
| 14 | Risk analysis (EN 12182, 4.1)<br>According to EN-ISO 14971 | conforms | pass |
| | | | |
| **EN 12184**<br>**8** | **Wheelchair performance** | | |
| **8.1** | **Performance of driving characteristics** | | |
| 8.1.1 | General<br>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.<br>Type class: B<br>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:<br>-The applicable rated slope for the type class of wheelchair specified in Table1, or<br>-The rated slope specified by the manufacturer, whichever is greater. | conforms<br>8,1km/h | 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 | 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<br>– 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%<br><br>116% | pass |

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<table>
<tr><td>8.1.5</td><td>Dynamic stability</td><td></td><td></td></tr>
<tr><td>8.1.5.1</td><td>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<br>– The applicable rated slope for the type of wheelchair specified in Table1, and<br>– the rated slope specified by the manufacturer.</td><td>conforms</td><td>pass</td></tr>
<tr><td>8.1.6</td><td>Obstacle climbing and descending</td><td></td><td></td></tr>
<tr><td>8.1.6.1</td><td>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.</td><td>conforms</td><td>pass</td></tr>
<tr><td>8.1.7</td><td>Static stability</td><td></td><td></td></tr>
<tr><td>8.1.7.1</td><td>The wheelchair shall meet or exceed the minimum requirements for static stability specified in Table 1 for the type class of the wheelchair.
<table>
<tr><td colspan="2" rowspan="2">Stability direction</td><td colspan="2">Tipping angle in °</td></tr>
<tr><td>Least stable</td><td>Most stable</td></tr>
<tr><td rowspan="2">Forward</td><td>Front wheels locked</td><td>9,5</td><td>>27,5</td></tr>
<tr><td>Front wheels unlocked</td><td>9,3</td><td>>27,5</td></tr>
<tr><td rowspan="3">Rear</td><td>Rear wheels locked</td><td>16,4</td><td>>27,5</td></tr>
<tr><td>Rear wheels unlocked</td><td>17,5</td><td>>27,5</td></tr>
<tr><td>Antitip devices a</td><td>N.A.</td><td>N.A.</td></tr>
<tr><td rowspan="2">Sideways</td><td>Left</td><td>15,7</td><td>23,0</td></tr>
<tr><td>Right</td><td>13,7</td><td>23,9</td></tr>
<tr><td colspan="4">a ‘least stable’ and ‘most stable’ refer to the positioning of the antitip devices (see 11.2.3 and 11.3.2).</td></tr>
</table></td><td></td><td>pass</td></tr>
<tr><td>8.1.8</td><td>Maximum speed</td><td></td><td></td></tr>
<tr><td>8.1.8.1</td><td>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.</td><td>10,8 km/h</td><td>pass</td></tr>
<tr><td>8.1.9</td><td>Distance range</td><td></td><td></td></tr>
<tr><td>8.1.9.1</td><td>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.</td><td>45,1 km</td><td>pass</td></tr>
</table>

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| | | | | |
|---|---|---|---|---|
| **8.2** | **Static, impact and fatigue strength** | | | |
| 8.2.1 | The wheelchair shall conform to the requirements of ISO 7176-8:1998. | Must comply with all requirements:<br>- static strength tests<br>- impact strength tests<br>- fatigue tests | <br>conforms<br>conforms<br>conforms | pass |
| | 8.4, Arm rests: downward | used load: 760 N | conforms | |
| | 8.5, Foot rests: downward | used load: 1000 N | conforms | |
| | 8.6, Tipping levers | | not applicable | |
| | 8.7, Handgrips | | not applicable | |
| | 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 | used: pendulum (83°) | conforms | |
| | 9.6, Foot rests impact | used: pendulum (83°) | conforms | |
| | 9.7, Front structure | used: pendulum (83°) | 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 intended | n.a. |
| **8.4** | **Climatic performance** | | | |
| | The wheelchair shall conform to the requirements of ISO 7176-9:2009<br>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 | 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 | 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 | pass |
| ISO 7176-9, 8.5 | Hot storage conditions, not less than 5 hours at 65 +/-5 °C, functional check after 1 hour | | conforms | 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 | pass |

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| EN 12184<br>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 | pass |
| 9.1.1 | Foot supports shall have means for preventing the user's feet from sliding backwards | conforms | pass |
| a) | Incorporate a means to locate it securely in any intended operating position | conforms | pass |
| b) | be adjustable in increments not exceeding 25 mm | conforms | pass |
| c) | be accessible and operable:<br>- by the occupant/assistant or both<br>- in accordance with the manufacturer's intended use of the wheelchair. | conforms | pass |
| d) | be within the reach space shown in Figure 1, and | conforms | pass |
| e) | be operable without the use of tools<br>The ability to make adjustments without the use of tools is not required. | conforms | pass |
| 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 | conforms | pass |
| 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. | conforms | pass |
| **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 | n.a. |
| **9.3** | **Pneumatic tyres** | | |
| | (if fitted with pneumatic tyres)<br>Shall have the same type of valve connections on all tyres.<br>Readily accessible<br>Tires or rims shall be marked with the maximum pressure in kPa or bar or PSI | not applicable | n.a. |
| **9.4** | **Anterior pelvic support** | | |
| | Shall have provision for an anterior pelvic to be fitted<br>Shall be available as option<br>And can be used with that provision | conforms | pass |

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| | | | |
|---|---|---|---|
| **9.5** | **Resistance to ignition** | | |
| 9.5.1 | Upholstered composite parts<br>shall be tested as specified in EN1021-2:2006 or ISO 8191-2:1988<br>(composites of cover and filling, with or without a support base or interliner)<br>Progressive smouldering ignition and flaming ignition shall not occur | conforms | pass |
| 9.5.2 | Foam Materials<br>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)<br>Progressive smouldering ignition and flaming ignition shall not occur | conforms | pass |
| 9.5.3 | Other parts<br>shall be tested as specified in EN 1021-2:2006 or ISO 8191-2:1988<br>(sling seats, sling backs, belts, restraint harnesses, foot supports, and clothing guards the material of each of them)<br>Progressive smouldering ignition and flaming ignition shall not occur | not applicable | n.a. |
| 9.5.4 | Power and control systems<br>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 | 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 | 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 | pass |
| 2) | be within the reach space shown in Figure 1, if the wheelchair is intended to be operated by the occupant; | conforms | pass |
| 3) | be within the reach space shown in Figure 3, if the wheelchair is intended to be operated solely by an assistant; | not applicable | n.a. |
| 4) | have operating forces for engaging and disengaging as stated in Table 1 when tested in accordance with 10.1.2: | | pass |
| | single finger 5 N | | n.a. |
| | more than 1 finger 13,5 N | 3,9 N | pass |
| | whole hand 60 N | | n.a. |
| | hand + arm 60 N | | n.a. |
| | foot, pushing 100 N | | n.a. |

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| | | | |
|---|---|---|---|
| | 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; | | n.a. |
| 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). | | n.a. |
| 10.1<br>(sub c) | Means for releasing parking brakes shall be protected against activation caused by accidental contact. | conforms | pass |
| **10.2** | **Braking functions**<br>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 | 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 | 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 | 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 | pass |
| e) | Parking brakes shall meet the parking brake effectiveness requirement in Table 1 when tested in accordance with 10.2.2.2. | conforms | pass |
| f) | Parking brakes shall be operable when there is no power from the battery supplying the drive system, | conforms | pass |
| g) | Parking brakes shall be operable when the wheelchair is in freewheel mode | conforms | pass |
| h) | If they are subject to wear, parking brakes shall have provision for adjustment and/or replacement as specified by the manufacturer. | conforms | pass |
| 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 | 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. | not applicable | n.a. |

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| 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. | not applicable | 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 | conforms | pass |
| | - be within the reach space shown in Figure 1, if the wheelchair is intended to be operated by the occupant | conforms | pass |
| | - be within the reach space shown in Figure 3, if the wheelchair is intended to be operated solely by an assistant | conforms | pass |
| | - have operating forces for engaging and disengaging that do not exceed those stated in Table 1 | conforms | pass |
| | - be operable without detaching any parts | conforms | pass |
| | - not depend on the battery power supplying the motor drive system | conforms | pass |
| | - have two defined positions including clear indication of freewheel mode and drive mode | conforms | pass |
| | - prevent use of the wheelchair's drive system, if the freewheel device is activated | conforms | 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 | pass |
| **11.2** | **Controls intended to be operated by the occupant** | | |
| | Controls intended to be operated by the occupant while seated shall be within the occupant reach space shown in figure 1.<br>The following controls, if fitted, are included: | | |
| | 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 | not applicable | n.a. |
| | direction switch | conforms | pass |
| | control device | conforms | pass |

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| | manual steering controls | conforms | pass |
| | lighting controls | not applicable | n.a. |
| | 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.<br>Examples include:<br>— brakes,<br>— control devices,<br>— push handles, and<br>— electrical ancillary equipment. | not applicable | 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.<br>When an assistant control unit is fitted,<br>- 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<br>- there shall be a means to support the assistant's hand or hands used to operate the control device. | not applicable | 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:<br>- a plane at 85° to the horizontal, that touches the rearmost points of the push handles as shown in Figure 6;<br>- 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;<br>- 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. |

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| **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. | conforms | pass |
| | single finger 5 N | | n.a. |
| | more than 1 finger 13,5 N | 11.6 N | pass |
| | whole hand 60 N | | n.a. |
| | hand + arm 60 N | | n.a. |
| | foot, pushing 100 N | | n.a. |
| | foot, pulling 60 N | | n.a. |
| | Turning knobs operated by one hand shall have:<br>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<br>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. | <br>2,75 Nm<br>n.a. | 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:<br>- attendant/user shall not have to lift a mass present a safety hazard | conforms | pass |
| | Controls intended to be operated by the occupant while seated shall be within the users reach. | conforms | 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.<br>The wheelchair and battery charger shall conform to the requirements of ISO 7176-21:2009.<br>In addition, wheelchairs that include an on-board battery charger shall conform to the applicable electrical requirements of EN 60601-1:2006 | conforms<br>conforms<br>not applicable | pass |
| **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.<br>Lights, direction indicators and hazard warning flasher functions shall not be affected by the operation of the means of protection of any other circuit.<br>Circuit protection devices that carry the total current of the battery set may be used. | conforms<br>conforms<br>conforms | pass |

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| **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:<br>- battery chargers shall indicate when charging is in progress and when charging is complete | conforms | pass |
| b) | Battery chargers shall have the capability of charging batteries discharged to 70 % of their nominal voltage; | conforms | 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 | 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 | 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. | conforms | 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 | 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.<br>Each emergency stop device shall:<br>— be clearly identifiable, clearly visible and quickly accessible by the intended operator, and<br>— stop the hazardous process as quickly as practicable, without creating additional risks. | conforms<br><br>conforms<br><br>conforms | 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.<br>It shall not be possible to engage the device without triggering a stop command.<br>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.<br>The emergency stop function shall be available and operational at all times, regardless of the operating mode.<br>Emergency stop devices shall be a back-up to other safeguarding measures and not a substitute for them. | conforms<br><br>conforms<br>conforms<br><br>conforms<br><br>conforms | pass |

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| **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 | 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 | 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.<br>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 | 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. | conforms | 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. | conforms | 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 | 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 | 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 |

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| 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 | available | 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) | 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.<br>This additional requirement may be reduced to some degree if an accurate charge level indicator is fitted | available | pass |
| 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 | | |
| 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 |

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| f) | the wheelchair manufacturer's recommended tyre pressure(s), expressed in kPa, bar or PSI | not applicable | n.a. |
| g) | instructions for dealing with tyre punctures, where pneumatic tyres are fitted | not applicable | n.a. |
| 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 | not applicable | n.a. |
| 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 |
| 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 | not applicable | 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 | available | pass |
| 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 | available | pass |
| 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 |

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| 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 | not applicable | n.a. |
| bb) | a warning if the adjustments of seating or wheel positions can be set outside safe limits | not applicable | n.a. |
| 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 | not applicable | n.a. |
| 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 | available | pass |
| hh) | the expected service life of the wheelchair | available | pass |
| ii) | the name and address of the manufacturer | available | pass |
| jj) | the name and address of the authorised representative, where the manufacturer does not have a registered place of business in the European Union | not applicable | n.a. |
| **13.4** | **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 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: | | |
| 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) | not applicable | 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 7176-15:1996 | available | pass |
| 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 | available | pass |

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| **EN 12182**<br>24 | **Requirements for information supplied by the manufacturer according to EN 12182:2012** | | |
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| 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 |
| | 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<br>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**<br>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. |

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| 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; | not applicable | n.a. |
| i) | If the assistive product is supposed to be used in combination with other products, the manufacturer shall state to which products, and how this can be done in a safe way | not applicable | n.a. |
| 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. |
| 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**<br>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 |

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| 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 |
| 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 | not applicable | n.a. |

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| | 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). | conforms | pass |
| | | | |
| | **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 | | |

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| | 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 | | |
| 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 |

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| | 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. | not applicable | 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. | 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 | | |
| | 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 |
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| | **ISO 7176-15:1996** | | |
| **ISO 7176-15 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 | conforms | pass |
| | b. the mass of the test dummy used in the test | conforms | pass |
| | either:<br>i) the performance values listed in annex A, in the order and using the wording shown, or<br>ii) if the part of IS0 7176 specifies a method of disclosure, that method shall have precedence over i) | <br>conforms<br>not applicable | <br>pass<br>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) | conforms | pass |
| | Folded width, (mm) | conforms | pass |
| | Folded height, (mm) | conforms | pass |
| | 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 |
| | 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 |

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| | Handrim diameter, (mm) | not applicable | n.a. |
| | Horizontal location of axle, (mm) | available | pass |
| | Minimum turning radius mm | conforms | pass |
| | The wheelchair conforms to the following standards:<br>1. requirements and test methods for static, impact and fatigue strengths (ISO 7176-8)<br>2. power and control systems for electric wheelchairs - requirements and test methods (ISO 7176-14)<br>3. climatic test in accordance with ISO 7176-9<br>4. requirements for resistance to ignition in accordance with ISO 7176-16. | <br>conforms<br>conforms<br>conforms<br>not applicable | <br>pass<br>pass<br>pass<br>n.a. |
| 7 | Documentation | | |
| 7.1 | General<br>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 | not applicable | n.a. |
| 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 |
| 7.2<br>7.2.1 | User manual<br>At least one copy of the user manual shall be supplied with each wheelchair.<br>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. | <br>conforms<br>conforms | <br>pass<br>pass |
| 7.3 | Contents of user manual | | |
| | 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 |

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| 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:<br>i) details of any maintenance, including: | conforms | pass |
| | - any service, maintenance | conforms | pass |
| | - information about needed to repair and service the wheelchair | conforms | pass |
| | - 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 |

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| | 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 | | |
| 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 |

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# 4 Remarks on the test results

| Req.nr. | Description of the requirement | Remark |
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| - | - | - |

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# 5 Conclusion

The wheelchair, trade mark: Medema, type: MC1124, meets the applicable requirements as stated in the European Standard EN 12184 [1] for a class B (indoor/outdoor) wheelchair.

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.

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# 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.

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## 7 Signatures

| **Author** | **Signature** |
|---|---|
| Mr. M.J.H. Braun, B.E.<br><br>Expert medical products |  |
| **Approved by** | **Signature** |
| Mr. T.W.J. Zandvliet, Bsc.<br><br>Expert medical products |  |

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## Appendix A, Pictures of the tested product








Picture(s) of the tested sample, trade mark: Medema, type: MC1124.

This is the end of this report.

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