

Document

Declaration of Conformity

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Issued By: Jinay Patel *Jinay R Patel* 11/12/19

Reviewed and Approved By: Ben Hemkens *Ben Hemkens* 11/12/19

Declaration of Conformity

for SmartDrive Wheelchair Power Assist System

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the product(s) described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

| | |
|---|---|
| General Product Name: | SmartDrive Wheelchair Power Assist System |
| Legal Manufacturer: (Name on Label) | Max Mobility, LLC 300 Duke Drive Lebanon, TN 37090 USA |
| Variants: | As per Appendix II (This document) = Product Listing/Schedule |
| Intended Use: | To provide auxiliary power to a manual wheelchair (As defined in the Classification Rationale Document(s) and other technical information in the Technical File(s) on file with the manufacturer) |
| MD Directive Classification: | Class I |
| Notified Body: | Not Applicable for Class I |
| EU Authorised Representative: | Advena Limited Tower Business Centre, 2 nd Floor Tower Street Swatar, BKR 4013 Malta |
| Medical Device Directive Assessment Route: | Self-certification by Medical Device Directive Annex VII; EC Declaration of Conformity and Article 14; Registration of persons responsible for placing devices on the market. |

Name *Darin Lowery*

Position *Sr VP Power Assist Products and BU-Manual*

Signed *[Signature]*

Date *11/13/19*

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

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Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

| Standard/Document Name | Description |
|------------------------|---|
| 93/42/EEC | Council Directive concerning medical devices as amended by Directive 2007/47/EC |
| EN 1041:2008 | Information supplied by the manufacturer of medical devices |
| EN ISO 14971:2012 | Medical Devices – Application of Risk Management to Medical Devices |

Product(s) conform to the following European / International Standards, either in their entirety or to the applicable parts:

| Standard/Document Name | Description |
|------------------------|--|
| EN 12184: 2014 | Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods |
| ANSI/RESNA WC-1: 2009 | Wheelchairs – Requirements and Test Methods for Wheelchairs (including Scooters) |
| ANSI/RESNA WC-2: 2009 | Wheelchairs – Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems |

Appendix II – Product Listing/Schedule

| Part/Catalogue Number | Description/Name | GMDN Code |
|-----------------------|--|-----------|
| MX1 | SmartDrive MX1 systems and parts manufactured 2012 to present | 42805 |
| MX1+ | SmartDrive MX1+ systems and parts manufactured 2013 to present | 42805 |
| MX2 | SmartDrive MX2 systems and parts manufactured 2015 to present | 42805 |
| MX2+ | SmartDrive MX2+ systems and parts manufactured 2017 to present | 42805 |
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Version History

| Version | Compiled by | Date | Description |
|---------|--------------|------------|--|
| 1.00 | Mark Richter | 8/6/14 | First issue |
| 2.00 | Mark Richter | 3/31/15 | Update to include MX2 model |
| 2.01 | Ben Hemkens | 1/3/17 | Update to include MX2+ model |
| 2.02 | Ben Hemkens | 3/14/18 | 2018 issuance; changes to Model Listing "Description/Name" to include "systems and parts" |
| 2.03 | Ben Hemkens | 5/18/18 | Revision and addition of "Standards tested to" |
| 2.04 | Ben Hemkens | 12/7/18 | All necessary revisions to coincide with and satisfy requirements for moving registration to "EU Authorized Representative" Advena office in Malta; update of "Legal Manufacturer" address |
| 2.05 | Jinay Patel | 11/12/2019 | Revision of "Appendix I – Applicable Standards"; Update to change legal person's name. |