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Document	Doc number.	Revision	Page
Declaration of Conformity	**DC001**	**2.05**	**1(3)**

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

Reviewed and Approved By: 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, 2nd 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 **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.

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.