MAX Mobility, LLC
Declaration of Conformity for SmartDrive Wheelchair Power Assist

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

European Communities Council Directive 93/42/EEC Concerning Medical Devices (including the revisions from Directive 2007/47/EC) as transposed into UK national law by the Medical Device Regulations.

The undersigned declares that the products 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

Manufacturer: MAX Mobility, LLC
5425 Crossings Blvd.
Antioch, TN 37013

Variants: As annexed to this declaration.

Intended Use: As defined in the Product Summary and Classification Rational Document.

Standards tested to: EN 12184: 2014

MDD Directive Classification No: Class 1 Device

Notified Body: N/A

EU Authorised Representative: Advena Ltd.
Registered office; Pure Offices, Plato Close Tachbrook Park, Warwick, CV34 6WE, UK

MDD Assessment route: Self certification by Annex VII, EC Declaration of Conformity and Article 14, Registration of persons responsible for placing devices on the market.

Signed ..... **Date** 1/3/17

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

Statement

This document is the MAX Mobility statement on the conformance of these medical devices to European Council Directive 93/42/EEC dated 14 June 1993 Annex VII paragraphs 3, 4 and 5 in reference to the application of an EC Declaration of Conformity.

3) The technical documentation must allow assessment of the conformity of the product with the requirements of the Directive. It must include in particular:

- a general description of the product, including any variants planned;

a) See page 1 of this Declaration and the annexed product list, the Classification Rationale Document, other technical information in the Technical File, plus additional documentation maintained by the manufacturer and/or their subcontractors. All variants are covered by this document.

- design drawings, methods of manufacture envisaged and diagrams of components, subassemblies, circuits, etc.;

b) Drawings, manufacturing and other specifications are filed with the manufacturer and/or their subcontractors, as controlled documents.

- the descriptions and explanations necessary to understand the above mentioned drawings and diagrams and the operations of the product;

c) Product manufacturing instructions, product user instructions, drawings and specifications are filed with the manufacturer and/or their subcontractors. Where necessary, instructions for use, including applicable technical information, will be available for each device.

- the results of the risk analysis and a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 have not been applied in full.

d) A risk analysis, and a MDD essential requirement check list, is maintained. General requirements for safety have been covered by testing and the products conform to the standards referenced on page 1 of this document.

- in the case of products placed on the market in a sterile condition, description of the methods used.

e) Not applicable.

- the results of the design calculations and of the inspections carried out, etc.; if the device is to be connected to other devices(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer;

f) These accessories may be used with other medical products and this has been considered in the risk management process.

-the test reports and, where appropriate, clinical data in accordance with Annex X;

g) Test Reports and clinical data, if applicable, on file with the manufacturer.

- the label and instructions for use;

h) As shown in the technical documentation on file with the manufacturer.

4) The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relating to the product. He shall notify the competent authorities of the following incidents immediately on learning of them:
i) any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which might lead to or might have led to the death of a patient or user or to a serious deterioration in his state of health;
ii) any technical or medical reason connected with the characteristics on the performance of a device for the reasons referred to in subparagraph (i) leading to systematic recall of devices of the same type by the manufacturer.

i) MAX Mobility maintains procedures for post market surveillance, device vigilance and the prompt handling, processing and analysis of customer complaints. Any technical reports, customer comments or dissatisfaction reports will be returned promptly to the manufacturer, either directly or via a representative or distributor, for review, comment and for any applicable device reporting and corrective or preventative actions.

With products placed on the market in sterile condition and Class I devices with a measuring function, the manufacturer must observe not only the provisions laid down in this Annex but also one of the procedures referred to in Annex IV, V or VI. Application of the above mentioned Annexes and the intervention by the notified body is limited to:
- in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions;
- in the case of devices with a measuring function, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

j) Not applicable.

ANNEX - Model Listing

Model	Description/Name
MX1	SmartDrive MX1 manufactured 2012 to present
MX1+	SmartDrive MX1+ manufactured 2013 to present
MX2	SmartDrive MX2 manufactured 2015 to present
MX2+	SmartDrive MX2+ manufactured 2017 to present