



**Tre Hargett**  
Secretary of State

**Division of Business Services**  
**Department of State**  
State of Tennessee  
312 Rosa L. Parks AVE, 6th FL  
Nashville, TN 37243-1102

## APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: United States of America
2. This public document has been signed by LISA CROWELL
3. acting in the capacity of COUNTY CLERK OF RUTHERFORD COUNTY, TENNESSEE
4. bears the seal/stamp of COUNTY SEAL OF RUTHERFORD COUNTY, TENNESSEE

### Certified

5. at Nashville, Tennessee
6. the 3rd day of February, 2022
7. by TRE HARGETT, SECRETARY OF STATE, STATE OF TENNESSEE
8. No. 22-02005

9. Seal/Stamp



10. Signature

*Tre Hargett*  
Secretary of State

by

*Jamie Burnett POA*

To verify authenticity, visit <http://tnbear.tn.gov/apostille/verify.aspx> and enter the document # (line 8 above) from this certificate. For further information please contact the Business Services Division at (615) 741-0536.

State of Tennessee  
County of Rutherford

I, Lisa Crowell, County Clerk, within and for the County and State aforesaid, the same being a Court of Record, do hereby certify, that Adam Katondress subscribed to the certificate of the proof of acknowledgement of the annexed instrument and thereon written, was, at the time of taking such proof and acknowledgement, a Notary Public, in and for said County, residing therein, duly commissioned and sworn, and authorized by the laws of said State, to take the acknowledgement and proofs of deeds and conveyances, for lands, tenements or hereditaments in said State, to be recorded therein. And further, that I am well acquainted with the hand-writing of said Notary Public, and verily believe that the signature to said certificate of proof or acknowledgement is genuine.

In Testimony Whereof, I have hereunto set my hand and affixed the seal of the said Court and County the 1<sup>st</sup> day of February, 2022

Lisa Crowell

Lisa Crowell, County Clerk

By: Imaundry

Deputy Clerk



Issued By: Jinay Patel

Reviewed and Approved By: Ben Hemkens

## Declaration of Conformity

for SmartDrive Wheelchair Power Assist System

**As a manufacturer, Max Mobility LLC declares that the SmartDrive Wheelchair Power Assist System is in conformity with the Regulation (EU) 2017/745 on medical devices (MDR)**

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

|  |   |
|--|---|
| <b>General Product Name:</b>               | SmartDrive Wheelchair Power Assist System   |
| <b>Legal Manufacturer: (Name on Label)</b> | Max Mobility, LLC<br>300 Duke Drive<br>Lebanon, TN 37090 USA  |
| <b>Variants:</b>                           | As per Appendix II (This document) – Product Listing/Schedule   |
| <b>Intended Use:</b>                       | 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) |
| <b>Product Class:</b>                      | Class I (According to Annex VIII Chapter III)   |
| <b>SRN</b>                                 | Advena Limited: MT-AR-000000234<br>Max Mobility SRN is not currently assigned. SRN will be assigned when EUDAMED is active  |
| <b>Notified Body:</b>                      | Not Applicable for Class I  |
| <b>EU Authorised Representative:</b>       | Advena Limited<br>Tower Business Centre, 2 <sup>nd</sup> Floor<br>Tower Street<br>Swatar, BKR 4013 Malta  |
| <b>Conformity Procedure Used</b>           | Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation in Annexes II and III of the EU MDR.  |

Name Ben Hemkens Position Director of Product Management

Signed  Date 2/1/2022

Issued By: Jinay Patel

Reviewed and Approved By: Ben Hemkens

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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2/1/22

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**Appendix I – Applicable Standards**

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

| Standard/Document Name   | Description   |
|--------------------------|---|
| Regulation (EU) 2017/745 | European Medical Device Regulations                                 |
| 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    | Basic UDI-DI       | UDI/GTIN Number | Description/Name  | GMDN Code |
|--------------------------|--------------------|-----------------|---|-----------|
| MX1<br>Parts/Components  | N/A                | N/A             | SmartDrive MX1 [Model] parts/components manufactured 2012 to present  | N/A       |
| MX1+<br>Parts/Components | N/A                | N/A             | SmartDrive MX1+ [Model] parts/components manufactured 2013 to present | N/A       |
| MX2<br>Parts/Components  | N/A                | N/A             | SmartDrive MX2 [Model] parts/components manufactured 2015 to present  | N/A       |
| MX2+                     | 08618960003SDMX237 | 00861896000310  | SmartDrive MX2+ [Model] systems                                       | 42805     |

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|                         |                   |                |  |       |
|-------------------------|-------------------|----------------|--|-------|
|                         |                   |                | manufactured 2017 to present   |       |
| MX2+ Parts / Components | N/A               | N/A            | SmartDrive MX2+ [Model] parts / components manufactured 2017 to present  | N/A   |
| MX2-167                 | 0850013215SDMX2PQ | 00850013215249 | SmartDrive MX2+ (Speed Limit) systems with SwitchControl Buttons & DE PushTracker 3 manufactured 2020 to present | 42805 |

**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 <b>Model Listing</b> "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.   |

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|      |             |            |  |
|------|-------------|------------|--|
| 2.06 | Ben Hemkens | 12/1/2020  | Revisions to "Appendix II – Product Listing/Schedule"; Update to change legal person's name.   |
| 2.07 | Jinay Patel | 04/20/2021 | Revisions to include MDR language within the DOC   |
| 2.08 | Jinay Patel | 04/26/2021 | Revisions to include the authorized representative's SRN and correct conformity assessment route   |
| 2.09 | Jinay Patel | 04/29/2021 | Revisions to include the Basic UDI-DI  |
| 2.10 | Ben Hemkens | 09/29/2021 | Revisions to update the MX2-167 Part/Catalogue Number to reflect change from PushTracker 2 component included in system to PushTracker 3 |

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2/1/22

COUNTY OF Wilson )

STATE OF TENNESSEE )

UNITED STATES OF AMERICA

I, Adam Latondress, a notary public in and for said County and State, do hereby certify that Ben Hemkens, personally known to me to be the same person whose name is subscribed to the foregoing instrument, appeared before me this day in person, and acknowledged that he is the Director of Product Management of Max Mobility, LLC, and that he signed and delivered the said instrument on behalf of said corporation by authority of its Board of Directors, and acknowledged said instrument to be the free act and deed of said corporation.

Given under my hand and official seal this 1 day of February 2022.

  
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Notary Public

My Commission Expires 6/18/2023

