

EU Declaration of Conformity

We, with the information specified in the below,

Our information as the manufacturer:

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|-----------------------------------|--|
| Manufacturer's Name: | KARMA MEDICAL PRODUCTS CO., LTD |
| Manufacturer's Address: | NO. 2363, Sec. 2, University Rd., Min-Hsiung Shiang, Chia-Yi County, 62144, Taiwan |
| SRN (Single Registration Number): | TW-MF-000013206 |

Our authorized representative:

| | |
|-----------------------------------|---|
| Name: | KARMA MOBILITY, S.L. |
| SRN (Single Registration Number): | ES-AR-000004852 |
| Address: | C/ PERIODISTA FRANCISCO CARANTOÑA DUBERT, 23 Bajo 33209 GIJÓN – ASTURIAS, SPAIN |
| Contact Person: | Raquel Yuste |
| Contact Information: | (+34) 984 390 907 |

in accordance with

Regulation (EU) 2017/745 of the European Parliament and of the council Annex I, II, III, IV and IX

hereby declare that the medical device specified below:

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|--|--|
| Basic UDI-DI of Annex VI: | 471987385KS-7M3 |
| Device: | Electrically powered scooter |
| Trade Name or Mark: | KS-7 series |
| Model Number: | KS-731, KS-737.2, KS-737.2L, KS-741, KS-747.2 |
| Product Code according to EMDN: | Y122124 |
| Product Code according to GMDN: | 45684 |
| Classification: | Rule 1 of Class I |
| UDI-DI: | 04719873857623, 04719873857630, 04719873857647, 04719873857654, 04719873857661 |

is in conformity with the applicable requirements of the following documents:

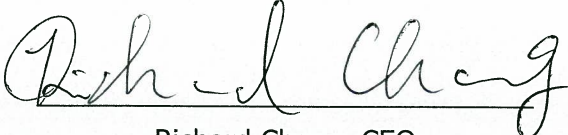
| Ref. No. | Title | Edition date |
|----------------------|--|--------------|
| ISO 13485 | Medical devices - Quality management systems - Requirements for regulatory purposes | 2016 |
| ISO 14971 | Medical devices - Application of risk management to medical devices | 2019 |
| EN 12182 | Assistive products for persons with disability - General requirements and test methods | 2012 |
| EN 12184 | Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods | 2014 |
| EN 62366 | Medical devices - Application of usability engineering to medical devices | 2015 |
| EN 60601-1 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | 2006 |
| EN ISO 10993-1 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process | 2009 |
| EN ISO 10993-5 | Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity | 2009 |
| EN ISO 15223-1 | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements | 2016 |
| MEDDEV. 2.7/1 Rev. 4 | CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS | 2016 |
| MEDDEV 2.12/1 Rev. 8 | GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM | 2013 |

The information on this declaration has been stated on the sole responsibility of KARMA MEDICAL PRODUCTS CO., LTD.

We hereby declare that the device named above has been designed to comply with the relevant sections of the above referenced specifications. The device complies with all General Safety and Performance Requirements.

Date of issue: 4th October 2021

Place of issue: NO. 2363, Sec. 2, University Rd., Min-Hsiung Shiang, Chia-Yi County, 62144,
Taiwan



Richard Chang, CEO