karma A Better Wheelchair, A Better Fit

Document No.: DOC-Leon F-01

EU Declaration of Conformity

We, with the information specified in the below,

Our information as the manufacturer:

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:

Basic UDI-DI of Annex VI:	471987385LeonF4C
Device:	Electrically powered wheelchair
Trade Name or Mark:	Leon F Kameleon series
Model Number:	Leon F Kameleon
Product Code according to EMDN:	Y122127
Product Code according to GMDN:	41637
Classification:	Rule 1 of Class I
UDI-DI:	04719873856855

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