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EU Declaration of Conformity

Document No. DOC-S-Ergo 100-00

We,

KARMA MEDICAL PRODUCTS CO., LTD

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

In accordance with the following directive

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

hereby declare that:

Basic UDI-DI of Annex VI:	471987385ErgoXT	
Equipment:	Manual wheelchair	
Trade name or mark:	S-Ergo 100 series	
Model Number:	S-Ergo 105(KM-1500.3)/S-Ergo 115(KM-1510.3) S-Ergo 106(KM-1501.3)/S-Ergo 125(KM-1520.3) S-Ergo 115TL(KM-1510.3TL)/S-Ergo 125TL(KM-1520.3TL)	
Product code:	(CND code) Y122103, Y122106 (GMDN code) 41622, 41630	
Directive Classification of Annex VIII:	Class I	
UDI-DI:	KM-1500.3	04719873857197
	KM-1510.3	04719873857227
	KM-1501.3	04719873857210
	KM-1520.3	04719873857234
	KM-1510.3TL	04719873857296
	KM-1520.3TL	04719873857302

European Representative:

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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 12183	Manual wheelchairs - Requirements and test methods	2014
EN 62366	Medical devices - Application of usability engineering to medical devices	2015
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
MEDDEV 2.12/2 Rev. 2	POST MARKET CLINICAL FOLLOW-UP STUDIES A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES	2012

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The unit complies with all applicable Essential Requirements of the Directives. The information that declaration has been stated on the sole responsibility of manufacturer.

Date of issue: 26th, May 2021

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

Kenny I.C. Chen, Chairman of the Board