

12. Overensstemmelseserklæring – MDR

El-kørestole og el-scootere der er til brug for fysisk handicappede er omfattet reglerne for medicinsk udstyr og skal være CE-mærkede.



CHIEN TI ENTERPRISE CO., LTD.

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Declaration of Conformity

MANUFACTURER			
Name of Company	Address	SRN	
Chien Ti Enterprise Co., Ltd.	No. 13, Lane 227, Fu Ying Rd., Hsin Chuang District, New Taipei City, Taiwan		

AUTHORIZED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone/fax/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands		+31.70.345.8570 - phone EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	Product Code / Catalog Number	Basic UDI-DI
CTM Mobility Scooter	HS-539	0850017490HS-539MD

Intended Purpose	Photo
The CTM Mobility Scooter Family provides a means by which a disabled occupant i.e. a disabled person or a person not having the full capacity to walk unaided to have mobility and the freedom to travel.	

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	Common Specifications
Class 1 Rule 13	EN 12184:2014

Chien Ti Enterprise Co., Ltd. declares that the above-mentioned products meet the provision of the following legislation:

MDR (EU) 2017/745 and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Route to conformance - Class I self-certified device follow Annex II and Annex III under the MDR

COMPANY REPRESENTATIVE: Vivian Lo

TITLE: Sales Director

SIGNATURE:

PLACE: Taipei, Taiwan

DATE: 10/16/2020