




CHIEN TI ENTERPRISE CO., LTD.

No. 13, Lane 227, Fu Ying Rd., Hsin Chuang District., New Taipei City, Taiwan
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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	TW-MF-000001535

AUTHORIZED REPRESENTATIVE		
Name of Company	Address	CHRN
MedNet EC-REP GmbH	Borkstrasse 10, 48163 Muenster, Germany	DE-AR-000000002

PRODUCT IDENTIFICATION		
Product Name	Product Code / Catalog Number	Basic UDI-DI
CTM Mobility Scooter	HS-758H Comet Ultra	0850017490HS-758HRK
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

Chien Ti Enterprise Co., Ltd. is exclusively responsible for the declaration of conformity.

COMPANY REPRESENTATIVE: Vivian Lo

TITLE: Sales Director

SIGNATURE:

PLACE: Taipei, Taiwan

DATE: 12/6/2022