



EU Declaration of Conformity



according to the Medical Device Regulation (MDR) 2017/745

Manufacturer	Everyway Medical Instruments Co., Ltd.
Address	3Fl., No.5, Ln. 155, Sec. 3, Beishen Rd., Shenkeng Dist., New Taipei City 22203, Taiwan
Registration No. SRN	TW-MF-00009887

Declared under the sole responsibility of the manufacture above mentioned.

For the following equipment :

Product	Accessories of Traction and Rehabilitation
Type designation (Catalogue No.)	Lumbar Traction Belt (2825 QUIKWRAP DTS BELT SYSTEM)
Classification (Intended purpose)	Class I (Annex VIII, Rule 1) Traction accessory designed to apply the traction or fix force to specific area of human body from external traction unit
Basic UDI-DI	471987118-TRACTION_ACC-ED
Trade name	EVERYWAY
Product code	Z12130285 (CND), 14100 (GMDN), 14100 (UMDNS)

has been assessed with respect to the conformity assessment procedures described in Article 10 and Article 19 together with Annex II & III of Medical Device Regulation (MDR) 2017/745, with

CE mark. Above mentioned designation complied with directive and harmonized standards as :

2011/65/EU (RoHS), EN1041:2008, EN ISO10993-1:2018, EN ISO10993-5:2009, EN ISO10993-12:2012,
EN ISO14971:2019, EN ISO15223-1:2016, EN60601-1-6:2010/A1:2015, EN62366-1:2015/A1:2020

also complied with non-harmonized standards as :

ISO10993-1:2018, ISO10993-5:2009, ISO10993-10:2010, ISO10993-12:2012, ISO14971:2019,
ISO15223-1:2016, IEC60601-1-6:2010/A1:2013/A2:2020, IEC62366-1:2015/A1:2020

Authorized representative established within the EU

Company name :	MDSS GmbH (SRN No.: DE-AR-000005430)
Company address :	Schiffgraben 41, 30175 Hannover, Germany

Responsible for making this declaration is: Everyway Medical Instruments Co., Ltd.

Person responsible for making this declaration

Name, Surname	:	Paul Hung
Position / Title :		QM Rep. / PRRC

Taipei

(Place)

Jul. 29, 2021

(Date)

(and legal signature)

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