CE 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 estabilshed 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)

Everyway Medical Instruments Co., Ltd.
3F., No. 5, Ln. 155, Sec. 3, Beishen Rd., Shenkeng Dist.,
New Taipei City 22203, Taiwan, R. O. C.
Tel : 886.2.2662.0038 .Fax : 886.2.2664 5566