



EU Declaration of Conformity




according to the Medical Device Directive 93/42/EEC as amended by
2007/47/EC

For the following equipment :

Product	Incontinence EMS with Probe Electrode
	Incontinence EMS: EV-805, EM-2400
	Probe electrode: PR-02,PR-02A,PR-02B,PR-02C,PR-03,PR-03A,PR-03B,PR-03C , PR-03G,PR-03H,PR-04,PR-04A,PR-04B,PR-04C,PR-04G,PR-04 H, PR-06,PR-06A, PR-06B,PR-06C,PR-06G,PR-06H,PR-07,PR-07A, PR-07B,PR-07C,PR-08A, PR-09A,PR-10A,PR-10D,PR-11A, PR-11D,PR-12A,PR-12D,PR-13,PR-13A,PR-13B,PR-13C,PR-14, PR-14A,PR-14B,PR-14C,PR-14D,PR-14E,PR-14G,PR-14H,PR-1 5A, PR-16A,PR-17A,PR-17B,PR-17C,PR-18,PR-19A,PR-19B,PR-19 C, PR-20,PR-20A,PR-20B,PR-20C,PR-20D,PR-20E,PR-20G,PR-20 H
Type Designation	
Classification	Class IIa (Rule 9 of MDD Annex IX)
Manufacturer & Sole responsibility	Everyway Medical Instruments Co., Ltd.
Address	3Fl. & 8Fl., No.5, Ln. 155, Sec. 3, Beishen Rd., Shenkeng Dist., New Taipei City 22203, Taiwan

has been assessed with respect to the conformity assessment procedures described in **Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Device, as amended by 2007/47/EC**, certificated by Notified Body: **DNV GL Presafe AS** (Address:Veritasveien 3, N-1363 Høvik, Norway) with **2460**

as identification number as 2460mark. Above mentioned designation complied with harmonized standards as :

- EN1041:2008, EN ISO10993-1:2009, EN ISO10993-5:2009, EN ISO10993-12:2012,
- EN ISO14971:2012, EN ISO15223-1:2016, EN60601-1:2006/A1:2013, EN60601-1-2:2015,
- EN60601-1-6:2010, EN60601-1-11:2010, EN60601-2-10:2000/A1:2001, EN62304:2006/
AC:2008,
- EN62366:2008

also complied with non-harmonized standards as :

- ISO10993-1:2009, ISO10993-5:2009, ISO10993-10:2010, ISO10993-12:2012, ISO14971:2007,
- ISO15223-1:2016, IEC60601-1:2005/A1:2012, IEC60601-1-2:2014, IEC60601-1-6:2010/
A1:2013,

IEC60601-1-11:2015, IEC60601-2-10:2012/A1:2016, IEC62304:2006/A1:2015,
IEC62366-1:2015

Responsible for making this declaration is the:

Authorized representative established within the EU

Company name : MDSS GmbH

Company address : Schiffgraben 41, 30175 Hannover, Germany

Person responsible for making this declaration

Name,
Surname : Bryce Hong

Position / Title : Business Development Manager

Taipei

(Place)

Aug. 30, 2019

(Date)



(Company stamp and legal signature)

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