CE 2460 EU Declaration of Conformity

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

Manufacturer	**Everyway Medical Instruments Co., Ltd.**
Address	**3Fl. & 8Fl., 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	**Incontinence EMS with Probe Electrode**
Type designation (Catalogue No.)	**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-04H, 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-15A, PR-16A,PR-17A,PR-17B,PR-17C,PR-18,PR-19A,PR-19B,PR-19C, PR-20,PR-20A,PR-20B,PR-20C,PR-20D,PR-20E,PR-20G,PR-20H**
Classification (Intended purpose)	**Class IIa (Rule 9 of MDD Annex IX)** **(EMS with Probe Electrode is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge and mixed urinary incontinence in women and to maintain urinary continence in women)**
Basic UDI-DI	**471987118-EMS-89, 471987118-INCONTINENCE-2Y, 471987118-PROBE-JW**
Trade name	**EVERYWAY**
Product code	**CND:** **J020401(Neurostimulator, urinary incontinence)** **U0780 (incontinence-control device, accessories) ,** **GMDN:** **65016 (Transcutaneous incontinence-control electrical stimulator)** **36050(Perineal orifice incontinence-control electrical stimulator electrode)** **UMDNS:** **17505(Stimulator, electrical, neuromuscular, incontinence, nonimplantable)** **13117 (Probes)**

We, the manufacturer declare that 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 CE 2460 mark.

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, EN60601-1-11:2015, 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

Authorized representative estabilshed within the EU

Company name : **Luana Med. B.V. (SRN No.: NL-AR-000002750)**

Company address : **Weena Zuid 130, 3012NC Rotterdam, Netherlands**

Person responsible for making this declaration

Name, Surname : **Jimmy Cheng**

Position / Title : **Quality Management Representative**

Jimmy Cheng

Taipei **Jan. 18, 2024** _____.

(Place) **(Date)** **(and legal signature)**