



EU Declaration of Conformity



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

For the following equipment:

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| Product | Transcutaneous Electrical Nerve Stimulator (T.E.N.S.) |
| Type Designation | N103A, N302, N601, N601-1, N601-2, N602, N603, N604, N608, E701, E702, E703, E704, EV-603M, EV-803, EV-803C, EV-804, EV-503, EV-503D, EV-803P, EV-904, EV-810, EV-820, EM-2200, EM-6100, MT-330, MT-330A |
| Classification | Class IIa (Rule 9 of MDD Annex IX) |
| Manufacturer | 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 Nemko Presafe AS with 2460 as identification number, above mentioned designation complied with harmonized standards as :

EN 980 :2008, EN 1041:2008, EN ISO 10993-1:2009, EN ISO 10993-5:2009,
 EN ISO10993-12:2009, EN ISO14971:2012, EN60601-1:2006/AC:2010, EN60601-1-2:2015,
 EN60601-2-10:2000/A1:2001, EN60601-1-4:1996/A1:1999, EN60601-1-6:2010,
 EN 60601-2-10:2000/A1:2001, EN 60601-1-11:2010, EN 62304 :2006/AC :2008

also complied with non-harmonized standards as:

ISO15223-1:2012, ISO10993-1:2009, ISO10993-5:2009, ISO10993-10:2010, ISO10993-12:2007,
 ISO14971:2007, ISO15223:2000, IEC60471-1:2002, IEC60601-1:2005, IEC60601-1-2:2014,
 IEC60601-1-4:1996/A1:1999, IEC60601-1-6:2010, IEC 60601-2-10: 2012, IEC60601-1-11:2010

Responsible for making this declaration is the:

Authorized representative established within the EU

Company name : REHAB EUROPA S.L.
 Company address : SANT GERVASI DE CASSOLES, 96 3º 4ª
 08022 BARCELONA, SPAIN.

Person responsible for making this declaration

Name, Surname : Paul Hung

Position / Title : Quality Management Representative

Taipei

(Place)

Dec. 21, 2017

(Date)

(Company stamp and legal signature)