Declaration of Conformity

For the following products:

Combo Electrotherapy Device

(Product Name)

R-C3, R-C4A and R-C4C

(Model Designation)

is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC)

Applicable harmonized standards are:

EN ISO 13485:2016
EN ISO 15223-1:2016
EN 1041:2008
EN ISO 780:2015
EN ISO 10993-1:2009/AC:2010
EN ISO 10993-5:2009
EN ISO 10993-10:2010
EN ISO 14971:2012
EN 60601-1:2006/A1:2013/AC:2014
EN 60601-1-2:2015
EN 60601-1-6:2010
EN 60601-1-11:2015
EN 60601-2-10:2015+A1:2016
EN 62304:2006/AC:2008
EN 62366-1:2015

Conformity Assessment Route:

Annex II excluding section 4 of Medical Device Directive

Notified Body:

DNV GL Presafe AS (NB No. 2460)
Veritasveien 3, 1363 Høvik, Norway

The following representative in Europe is responsible for making this declaration:

Company Name: Shanghai International Holding Corp. GmbH (Europe)

Company Address: Eiffestrasse 80, 20537 Hamburg, Germany

The following manufacturer is exclusively responsible for making this declaration:

Company Name: Shenzhen Roundwhale Technology Co., Ltd.

Company Address: 202, 2/F, Building 27, Dafa Industrial Park, Longxi Community, Longgang District, Shenzhen 518000, China

(Legal Signature)

Vice President

(Position/title)

2020.6.16

(Date)