Declaration of Conformity

For the following products:

Combo Electrotherapy Device
(Product Name)
R-C4A
(Model Designation)
697176360CE000173
(Basic UDI-DI)
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 Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices.

Applicable harmonized standards
EN ISO 15223-1:2021, EN ISO 20417:2020, IEC 60601-1:2005+AMD2:2020, EN 60601-1-2:2015+A1:2021, IEC 60601-2-10:2012+A1:2016, IEC 60601-1-11:2015+AMD1:2020, IEC 62304:2006+A1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021,EN 62366-1:2015+A1:2020, EN ISO 14971:2019, ISO/TR 24971:2020, ASTM D4169-2022.

Product Code

GMDN Code:	46573
GMDN Term:	Physical therapy transcutaneous neuromuscular electrical stimulation system
EMDN Code:	Z120628
EMDN Term:	Neuromuscular stimulation equipment

Conformity Assessment Route:
Annex IX chapter I + chapter III of Regulation (EU) 2017/745

Risk class of the device in accordance with the rules:
Rule 9 IIa
Notified Body:
DNV Product Assurance AS (NB No. 2460)
Veritasveien 1, 1363 Høvik, Norway

The following European Authorized Representative is stated to the declaration:
Company Name: Shanghai International Holdings Corp. GmbH (Europe)

Company Address: Eiffestrasse 80, 20537 Hamburg, Germany

Single Registration Number (SRN): DE-AR-000000001

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, China

Single Registration Number (SRN): CN-MF-000021504

Baird Zeng

(Legal Signature)

Management representative

Shenzhen

(Position/title)

2026.6.28

(Date)