

Declaration of Conformity

For the following products:

Combo Electrotherapy Device

(Product Name)

R-C1

(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.

Intended purpose:

The device is designed to be used for temporary relief of pain, including the acute and chronic pain relief.

The device is designed to be used for stimulate muscles for prevention of muscular atrophy, muscle strengthening and improve, increasing local blood circulation and facilitate muscle performance.

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

EU Quality Management System Certificate:

Certificate no.:C544552 Initial certification date:27 June 2024 Valid Until:27 June 2029

The following European Authorized Representative is stated to the declaration:

Company Name: Shanghai International Holding 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

June Zhou

(Legal Signature)

Regulatory Affairs

(Position/title)

2025.2.28

(Date)