

Declaration of Conformity

Manufacturer:

Shenzhen Roundwhale Technology Co., Ltd.
202, 2/F, Building 27, Dafa Industrial Park, Longxi Community, Longgang District, Shenzhen 518000,
China
SRN:CN-MF-000021504

EU Representative:

Shanghai International Holding Corp. GmbH(Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
SRN:DE-AR-000000001

Product Name: NEUROLOGICAL PHYSIOTHERAPY DEVICES - ACCESSORIES

Product code / Catalogue number:

Gloves AC4001, Socks AC5001, Knee Belt AC 3002, Elbow Belt AC 3003,
Joint Belt AC3001, Back Belt AC2001, Abdomen belt AC1001,P50100 Electrodes.

Basic UDI-DI:697176360PAD0001HT

EMDN code: N010280- NEUROLOGICAL PHYSIOTHERAPY DEVICES - ACCESSORIES

Classification:Class I, rule 1 of Term 4 of Annex VIII of MDR 2017/745

Conformity assessment procedure: Annex II + Annex III of MDR 2017/745

Notified Body name	N/A
Notified Body name	N/A
Notified Body Identification number	N/A
(EC) Certificate(s)	N/A
Start of CE-marking:	2023-04-26

We, the manufacturer, hereby declare that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

 July 18, 2023
Authorized Signature & Stamp (Vice President)

