

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: Self-adhesive Electrode Pads

Product code / Catalogue number:

P4040\P5050\ P4080\ P50100\R3232\R4040\R5050

Basic UDI-DI: 697176360PAD0001HTM

EMDN NO: N10201 TENS SYSTEM ELECTRODES

Intended Use:

Self-adhesive Electrode Pads are intended to transmit electrical current to patient skin for using with Transcutaneous Electrical Stimulation devices. The Self-adhesive Electrode Pads are used with some common types of the stimulation devices, including but not limited to TENS(Transcutaneous Electrical Nerve Stimulation),MIC,RUSS,IF and EMS (Electrical Muscle Stimulation). The Self-adhesive Electrode Pads are for OTC (Over-The -Counter) or Prescription use


Applied Standard & Common Specification:

EN ISO 13485:2016,EN ISO 15223-1:2021,EN ISO20417: 2021,EN ISO 14971:2019, EN ISO 10993-1:2020, EN ISO 10993-5:2009,EN ISO 10993-10:2021,EN ISO 10993-23:2021, ASTM F 1980-21.

Classification acc. To MDR Ax. VIII: Class I, rule 1 of Term4 of Annex VIII of MDR 2017/745
Conformity assessment procedure: N.A.

CE Certificate No.: N.A.

We, the manufacturer, herewith declare under our sole responsibility 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.

Baird Zeng 
Authorized Signature & Stamp (Vice President)Shenzhen 2022/7/13