

CE EU Declaration of Conformity CE

According to the Medical Device Regulation (MDR) 2017/745

Manufacturer: GMDASZ Manufacturing Co., Ltd.

Address: E-1308, Xihaimingzhu Building, Nanshan District, Shenzhen, China

Single Registration Number (SRN): CN-MF-000011760

Declared under the sole responsibility of the manufacturer above mentioned for the following equipment:

Product: Transcutaneous electrical stimulation electrode, reusable

Classification: Class I (According to Annex VIII, Rule 1)

Intended Purpose: Skin electrodes designed to apply electro-stimulation to nerves or muscles from external neuromuscular stimulators

Basic UDI-DI: 697034167099HN

Product Name: Transcutaneous electrical stimulation electrode, reusable

Trade Name: Stadtholder, Qines


Catalog Number (Type Designation): CWN2505, CWN1003, CWN2509, CWN2205, CWN3510, DWF1015 / 610032-B, 610034-B, 614060-B, 615050-B, 615090-B, 6150105-B

Product Code: GMDN Code: 65318,

GMDN Term: Transcutaneous electrical stimulation electrode, reusable

EMDN Code/CDN code: N010201

EMDN Term/CDN Term: TENS SYSTEM ELECTRODES

has been assessed with respect to the conformity assessment procedures described in Article 10 and Article 19 together with Annex II & III of Medical Device Regulation (MDR)2017/745, with  mark. Above mentioned designation complied with harmonized standards as:

EN1041:2008, EN ISO10993-1:2018, EN ISO10993-5:2009, EN ISO10993-12:2012, EN ISO14971:2019,

EN ISO15223-1:2016, EN60601-1-6:2010/A1:2015, EN62366-1:2015/A1:2020

Also complied with non-harmonized standards as:

ISO10993-1:2018, ISO10993-5:2009, ISO10993-10:2010, ISO10993-12:2012, ISO14971:2019, ISO15223-1:2016, IEC60601-1-6:2010/A1:2013/A2:2020, IEC62366-1:2015/A1:2020

Responsible for making this declaration is the: Authorized Representative established within the EU

Company Name: EUROBYTECH

Single Registration Number (SRN): FR-AR-000002404

Company Address: 88 RULE DE LA LIBERTE 71000 MACON, FRANCE

Person responsible for making this declaration:

Xiangjie Zhang


(Name, Surname)

(and Legal Signature)

August 23,2023

Date

Shenzhen

Place

Position/Title: President

