DECLARATION OF CONFORMITY

TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES

MANUFACTURER: **Shenzhen Kentro Medical Electronics Co., Ltd.**

2nd Floor, No. 11, Shanzhuang Road, Xikeng Village, Yuanshan Street, Longgang District, Shenzhen City, Guangdon Province, China.

Medical Device: Transcutaneous Electrical Nerve Stimulators

Model: KTR-2401, KTR-2492, KTR-405, KTR-230, KTR-2302 (Paingone Easy, Paingone Aegis, Paingone FIlow, Paingone XL, Paingone Ellune)

Classification - Annex IX: class IIa, rule 9

Conformity assessment Route: Annex II excluding 4

We, Shenzhen Kentro Medical Electronics Co., Ltd., here with declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC concerning medical devices;

All supporting documentation is retained at the premises of the manufacturer.

Standards applied: 93/42/EEC, EN ISO14971, EN1041, EN 60601-1, IEC 60601-1-6, EN 60601-1-2, IEC 62304, EN 62366-1, IEC 60601-1-11, MEDDEV 2.7.1, EN ISO 10993-1.

Notified Body: INTERTEK SEMKO AB

ADDRESS: TORSHAMNSGATAN 43 BOX 1103, SWEDEN

SE-164 22 KISTA

identification number: CE 0413

(EC) Certificate(s): ISO 13485

EC REP

European Representative:

WellKang Ltd (www.CE-marking.eu)

Enterprise Hub, NW Business Complex,

1 Beraghmore Road,Derry, BT48 8SE,

Northern Ireland

Start of CE-marking:

Place, Date of Declaration: China 2023-02-23

Signature: Zewu zhang position: General Manager name: Zewu Zhang