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 Stimulator

Models: KTR-401, KTR-402, KTR-403, KTR-405

Classification - Annex IX: class IIa, rule 9

Conformity assessment Route: Annex II excluding 4

GMDNS code: 32554

WE, **Shenzhen Kentro Medical Electronics Co.,Ltd.**, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICESMEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES, AND COMPLY WITH THE RELEVANT REQUIREMENTS OF THE SWEDISH NATIONAL LEGISTLATION LVFS 2003:11 TRANSPOSING OF THE EUROPEAN MEDICAL DEVICES DIRECTIVE, MDD93/42/EEC;INCLUDING,AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC. ALL SUPPORTING DOCUMENTATION IS RELAINED AT THE PREMISES OF THE MANUFACTURER.

Notified Body: INTERTEK SEMKO AB

identification number: CE 0413

(EC) Certificate(s):

EC REP

European Representative: Wellkang Ltd
The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland

Start of CE-marking:

Place, Date of Declaration: China 2021-03-23

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