

Shenzhen Kentro Medical Electronics Co.,Ltd.	CE Technical File	File No	A014	Version	A3
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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, Guangdong 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 DEVICES MEET 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 LEGISLATION 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:  0413

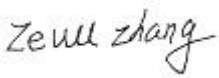
(EC) Certificate(s):



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:  position: General Manager name: Zewu Zhang