DECLARATION OF CONFORMITY

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

MANUFACTURER: **Shenzhen Kentro Medical Electronics Co., Ltd.**
No.3, Xihu industry zone, Xikeng Village, Henggang Town, Longgang District, Shenzhen, Guangdong, China.

Medical Device: Transcutaneous Electronic Nerve Stimulator
Model: Aegis/ KTR-2492
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
16 Castle St, Dover, CT16 1PW, UK & Suite B, 29 Harley St, London, W1G 9QR, UK
The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland

Start of CE-marking:

Place, Date of Declaration:

Signature: Zewu Zhang Position: General Manager Name: Zewu Zhang

Shenzhen Kentro Medical Electronics Co., Ltd.