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# EC CERTIFICATION

## FULL QUALITY ASSURANCE SYSTEM

### Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

**Organization:**

## SHENZHEN KENTRO MEDICAL ELECTRONICS CO., LTD.

N0.3, Xihu industry zone, Xikeng Village, Henggang Town, Longgang District, Shenzhen City, Guangdong province, China

**Product Category:**

- Transcutaneous electrical nerve and muscle stimulators

For further identification of the products covered, see the MDD product list/product schedule.

**Certificate Number:**
41371473-01

**Initial Certification Date:**
January 26, 2018

**Certificate Valid from:**
March 19, 2018

**Certificate Expiry Date:**
January 25, 2023

SWEDAC ACKREDITERING
Ackred. nr 1003
ISO/IEC 17021

**Peter Nermander**
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

March 19, 2018
**Signed Date**

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The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.