Shenzhen Kentro Medical Electronics Co., Ltd

EC DECLARATION OF CONFORMITY

We, **Shenzhen Kentro Medical Electronics Co., Ltd** (Add.: No. 3, Xihu industrial Park, Xikeng Village, Henggang Town, Longgang District, ShenZhen, China) hereby declare that the product described below:

Transcutaneous Electrical Nerve Stimulator

Model Identification:

Paingone Easy (as well as Paingone XL/KTR-230)

Starting from the batch no. LOT201810077 is compliant with:

- The essential requirements of the EEC 93/42 Directive and its subsequent additions, including the EC 2007/47, concerning Medical Devices.
- The Standard EN 14971:2012- Risk Management of Medical Devices
- The Standard IEC 60601-1:2006/A11:2011/A1:2013 IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- The Standard IEC 60601-1-2:2015- Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard Electromagnetic disturbances - Requirements and tests.
- The Standard IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- The Standard IEC 60601-1-6:2011- Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- The product has been classified on class IIa according to the Council Directive 93/42/EEC and it is certificate following the Annex V of the same Directive by the Notified Body CE0123.

The Legal Representative

Shenzhen Kentro Medical Electronics Co.,Ltd

2019-5-21