EEC DECLARATION OF CONFORMITY

CE

We, **ITALQUARTZ S.R.L** Via del Colle 101,50041 Calenzano (FI) Italia, hereby declare that the product described below:

TRANSCUTANEOUS STIMULATOR

Model Identification:

PAINGONE +/ PAINGONE PLUS

Starting from the batch nr. **PGP 180001** is compliant with:

- The essential requirements of the EEC 93/42 Directive and its subsequent additions, including EC 2007/47, concerning Medical Devices, and its implementation in Italy with D.Lgs 46/97 and its subsequent additions, including the D.Lgs 37 / 10
- 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 class IIa according to the Council Directive 93/42/EEC and it is certified following Annex V of the same Directive by the Notified Body **CE1282** - Ente Certificazione Macchine Via Ca' Bella,243-Comune Valsamoggia 40053 Loc. Castello di Seravalle (BO) Italy.

The Legal Representant

Calenzano, 13/02/2018