GYENNO

Declaration of Conformity

Manufacturer:
GYENNO Technologies CO., LTD.
A805 A806, Shenzhen Institute of Industry-University-Research of HUST, No.9 Yuexing 3rd Road, Science Park, Nanshan District, Shenzhen, 518000, P. R. China.

EC Representative:
MedNet EC-REP GmbH
Borkstrasse 10, 48163 Münster, Germany

Device Name and Type:

Device Name: Hand Tremor Data Collector

Model: TC200

Base UDI： 06970096280157

Classification and Conformity Route:
According to Regulation （EU） 2017/745 Annex VIII, Rule 13, the Hand Tremor Data Collector is a class I device. The Conformity Route is Annex II and III.

We, the manufacturer herewith declare on our solo responsibility that the above mentioned products meet the provisions of the Council Regulation 2017/745 for medical devices. All supporting documentation is retained under the premises of the manufacturer.

The validity period of this declaration of conformity is limited by the issuing of a revised declaration of conformity after change of the product.

Harmonized Standards:
All applicable harmonized Standards (published in the Official Journal of the European Communities)
Please see Annex List.

Signature: Qiaojuan. Liu **Date:** DEC 15. 2021

Name/Position: Liu Qiaojuan/Management representative
Place: Shenzhen

Annex:

Harmonized Standards List

Standards code	Standard's title
EN 60601-1: 2006 +A11:2011+A1:2013+A12:2014	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2: 2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
EN 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
EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10: 2013	Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization
EN 62304: 2006/A1:2015	Medical device software – Software life-cycle processes
EN ISO 14971: 2019	Medical devices – Application of risk management to medical devices
EN 60601-1-6:2010/A1:2015	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN 62366-1:2015/AC:2015	Medical devices – Part 1: Application of usability engineering to medical devices
EN ISO 15223-1: 2021	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices.
EN ISO780:2015	Packaging – Distribution packaging – Graphical symbols for handling and storage of packages.
MEDDEV 2.7.1: 2016	Clinical evaluation: a Guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
MEDDEV 2.12	Guidelines on a medical devices vigilance system