EC Declaration of Conformity

Manufacturer:	**European Representative*:***	**Swiss Representative*:***
Name: GYENNO Technologies CO.,LTD. *Address:801-804 & 904, Building B2, Phase II, Creative City, Xian Dong Road, Xili Street, Nanshan District, Shenzhen, 518055, Guangdong, P.R. China* *SRN:CN-MF-000019513*	*Name:MedNet EC-REP GmbH* *Address:Borkstrasse 10,48163 Muenster,Germany* *SRN:DE-AR-000000002*	*Name:MedNet SWISS GmbH* *Address:Bäderstrasse 18, 5400 Baden, Switzerland*

Product Name:*Hand Tremor Data Collector*

Models:*TC200*

Basic UDI: *697009628TC25*

Intended use:*The hand tremor data collector is used to collect hand tremor data of user with Parkinson's Disease, Parkinson’s Syndrome, Essential Tremor, or other physical disabilities. It can also be used as an assistive equipment to eat.*

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 declare on our own responsibility that the medical device above meets all the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, which apply to it.

EMDN Code:*V9099*

EC regulation: Medical Device Regulation, (EU)2017/745.

CE

The product identified above complies with the general safety and performance requirements of the above EC regulation by meeting the following standards:

EN ISO 13485:2016；EN ISO 14971:2019；EN ISO 15223-1:2021；EN ISO 20417:2021；EN 60601-1:2006+A1:2013+AC:2014+A12:2014 +A2:2020; EN 60601-1-2:2015+A1:2020; EN 60601-1-6:2010+A1:2015+A2:2020 ; IEC TR 62366-2:2016;EN 60601-1-11:2015+A1:2020 ; IEC 62304:2006/AMD1:2015; EN 62366-1:2015+A1:2020；EN ISO 10993-1:2020;EN ISO 10993-5:2009;EN ISO 10993-10:2013;MDCG 2023-3_QandA vigilance MDR;Medical Devices Ordinance 1 July 2020（MedDO）

The above mentioned declaration of conformity is exclusively under the responsibility of

GYENNO Technologies CO.,LTD.
Nanshan District,Shenzhen,518055,China

Signature: Liu Qiaojuan ***Date:*** *21.06.2023*

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