DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021
EN 60601-1-2:2015/A1:2021
EN 60601-1:2006/A2:2021
EN 12184: 2022

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122127-01.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: Super Pi Robot（China） Co., Ltd
Address: Room 301, 3rd Floor,Building 4,Jingcheng Technology Park,No.2630 Yuhangtang Road,Yuhang Distric,Hangzhou City, Zhejiang Province,China
SRN: CN-MF-000036567

Product Information

Name： SUPER PI intelligent electric wheelchair
Model： MODEL Y、MODEL P2
EMDN： Y122127
Basic UDI-DI： 697668065SPIEW001RK
Classification: Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:

Position: GM

Date: 2024.6.26

Place: Hangzhou/China