DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
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SRN: NL-AR-000000247

Manufacturer

Name: Nanjing MIJO Technology Co., Ltd
Address: Building A3-2, Yongning Intelligent Manufacturing Industrial Park, No. 77 Hupo Road,Nanjing City,China
SRN:CN-MF-000045271

Conformity Assessment

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

Applicable Standards
EN ISO 14971: 2019+A11:2021
EN ISO 15223-1:2021+A1:2025
EN ISO 20417:2021
EN ISO 10993-1: 2025
EN ISO 10993-5: 2009+A11:2025
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021+A1:2025
EN 60601-1:2006+A13:2024
EN 60601-1-2:2015+A1:2021
EN 12184:2022

Product Information

Name: Power Handbike For Wheelchair
Model:
MT01,MT02,MT03,MT04, MT05, MT06,MT07,MT08, MT09, MT10
EMDN: Y122410
Basic UDI-DI: 697807460PHFW001YE
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.

Remark

The declaration of conformity is valid in connection with the release technical document MDR-TCF-001.

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.

Signature: Date:2026.5.14

Position: GM Place: NANJING/CHINA

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