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/A11:2021
ISO 15223-1:2021/Amd 1:2025
EN ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5:2009/A11:2025
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021
EN 60601-1:2006/A13:2024
EN 60601-1-2:2015/A1:2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-V080503-01.

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: Wiseton Industries Limited
Address: No.9 Jiahe Road, Jiashan County, Jiaxing City, Zhejiang Province, P.R. China
SRN: CN-MF-000040574

Product Information

Name: Electric Patient Lift
Model: PL300, PL301, PL350
EMDN: V080503
Basic UDI-DI: 697690461300ND
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:

Date:2025.9.18

Position: GM

Place: Zhejiang/China