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

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z12030285-01.

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: Shenzhen UpnMed Equipment Co., ltd
Address: No.301, Building #41st, The 3rd Industrial Zone, Xitian Community, Gongming Street, Guangming District, Shenzhen, China, zip: 518106
SRN: CN-MF-000019212

Product Information

Name：Blood Pressure Cuff
Model：U500-1T、U500-2T、U500-1L、U500-2L、U500-1A、U500-2A、U500-1P、U500-2P、U500-1Y、U500-2Y、U500-1N、U500-2N
EMDN：Z12030285
Basic UDI-DI：697040488BPC001B2
Classification: Class I, According to Rule 1, 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:2026.6.09

Position: Sales Manager Place: Shenzhen /China

UpnMed Equipment Co., Ltd 深圳市优品医疗设备有限公司 Shenzhen