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 60601-1:2006/A2:2021
EN 60601-1-2:2015/A1:2021

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：ECG Cable

Model：U101-3A3SA、U101-3A5SA、U101-3A7SA、U101-3A10SA、U102-1110SA、U103-113SA、U104-115SA、U142-1110SA、U145-12A7A、U165-13SA、U172-1110SA、U1108-117SA、U1108-1110SA、U1109-1110SA；U202-11BE、U202-22GA、U202-21BE、U202-31BA、U203-11BE、U204-11BA、U205-11DA、U205-41BA、U215-11BA、U223-11SA、U225-11DA、U227-11BA、U229-11BA、U235-11BA、U238-11BA、U242-11BA、U244-11DE、U245-11SA、U246-11BE、U247-11BE、U254-11BA、U257-11DA、U261-11BE、U269-11BA、U272-11BA、U273-11BE、U290-11BA、U295-11BE；U301-13SA、U301-15SA、U302-23SA、U302-25SA、U302-22G5A、U303-23SA、U303-25CE、U303-3D3SA、U303-3D5CE、U303-12D3AE、U303-12D5AE、U304-3P3CA、U304-3P5CE、U304-23SA、U304-25SA、U305-13SA、U305-15SE、U305-3F3SA、U305-3F5SA、U305-32F6A、U306-13SA、U306-15SE、U306-12C3A、U306-12C5A、U307-13SA、U307-15CE、U309-13SA、U309-15CE、U315-13SE、U315-15CA、U315-22E5AE、U325-13SE、U325-15SE、U327-13CA、U327-15SE、U338-13SA、U338-15SA、U367-13SE、U367-15SA、U369-13SE、U369-15SE、U373-13SA、U373-15SE、U383-14SA、U383-16SE、U3112-13SA、U3112-15SE

EMDN: Z12030680

Basic UDI-DI: 697040488EC0018Q

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:2026.6.09

Position: Sales Manager Place: Shenzhen /China

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

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Z12030680-01.

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.