



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: 2013
EN 868-5:2019

Remark

The declaration of conformity is valid in connection with the release technical document [CE/MDR-S0101-02](#).

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: ANHUI PUTIAN PLASTIC INDUSTRY CO., LTD
Address: EAST BATIAN STREET, DATONG TOWN, TIANCHANG, ANHUI PROVINCE, CHINA
SRN: CN-MF-000032437

Product Information

Name: STERILIZATION ROLL
Model: PTFSR PTGSR PTTSR
EMDN: S0101
Basic UDI: 697630034RoI1001LX
Classification: 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:

Position: GM

Date: Nov.31, 2022

Place: Anhui/China

