DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

Digitally signed by Potînga Stela
Date: 2026.04.16 14:16:09 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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: 2016
EN ISO 20417:2021
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN12184:2014

Remark

The declaration of conformity is valid in connection with the release technical document CE-MDR-TCF01.

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

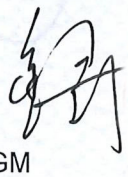
Name: NINGBO KS MEDICAL TECH CO.,LTD
Address: Building 1, No.462 Wenyuan Road, Yinzhou District, Ningbo, China

Product Information

Name : SURGICAL
Model : KSM-MT7 304 and KSM-MT8 304
Trade name: STERILIZER INSTRUMENT
GMDN : 45684
Basic UDI-DI : 69721189800RAA8C
SRN: CN-MF-000009846
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: 2021.09.21

Position: GM Place:Shenzhen/China