



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

Manufacturer

Name: SHENZHEN YONGCHANGHE
TECHNOLOGY CO., LTD.
Address: 1001, HUAIDE INTERNATIONAL
BUILDING, NO. 73, FUYONG SECTION,
GUANGSHEN ROAD, FUYONG COMMUNITY,
FUYONG STREET, BAO'AN DISTRICT, SHENZHEN,
CHINA 518103
SRN: /

Product Information

Name: Surgical Guide Resin
Model: DB-07 or Customized
EMDN: Q01020501
Basic UDI-DI: /
Classification: Class I, According to Rule 5, Annex
VIII, Regulation (EU) 2017/745

Declaration

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Q01020501-01.

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.

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: 2023.8.11

Position: GM

Place: Shenzhen/China



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