



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-Q0102050101-01.

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 YONGCHANGHE TECHNOLOGY CO.,LTD.
Address: 1001, HUAIDE INTERNATIONAL BUILDING, NO. 73, FUYONG SECTION, GUANGSHEN ROAD, FUYONG COMMUNITY, FUYONG STREET, BAO'AN DISTRICT, SHENZHEN, CHINA
SRN: CN-MF-000037344

Product Information

Name: Crown & Bridge Resin (C&B Resin)
Model: DF-A0、DF-A1、DF-A2、DF-A3 、DF-A4、DF-A5、DF-A6、DF-A7、DF-A8、DF-A9、DF-A10、DF-B0、DF-B1、DF-B2、DF-B3、DF-B4、DF-B5、DF-B6、DF-B7、DF-B8、DF-B9、DF-B10 or customized
EMDN: Q0102050101
Basic UDI-DI: 697669345DFseriesSX
Classification: Class I, According to Rule 5, 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: 2023.10.31

Position: GM Place: Shenzhen/China