



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+A11:2021

EN ISO 15223-1:2021+A1:2025

EN ISO 20417:2026

EN ISO 10993-1: 2025

EN ISO 10993-5: 2009+A11:2025

EN ISO 10993-10: 2023

EN ISO 10993-23: 2021+A1:2025

EN 14683:2025

Remark

*The declaration of conformity is valid in connection
with the release technical document
MDR-TCF-002*

*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.*

File No.: MDR-TCF-002-08

Manufacturer

Name: Rizhao Sanqi Medical & Health Articles Co.,
Ltd.

Address: No. 137, Rizhao North Road, High-tech
Zone, Rizhao City, Shandong Province

SRN: CN-MF-000008918

Product Information

Name: DISPOSABLE SURGICAL FACE MASK

Model: SQ2001 (L: 17.5cm*9.5cm, M: 14.5*9.5cm,
S: 12.5*9.5cm)

EMDN: T020604

Basic UDI: 69563824surgicalTQ

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: *Julia Yu* Date: 2026/4/27



Position: GM

Place: Shandong/China