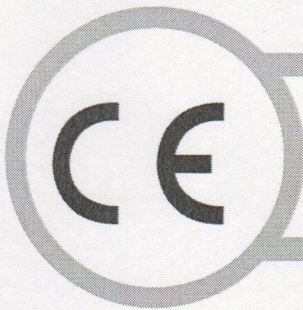




# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Europe B.V.

Fascinatia 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 13795-1:2025

## Remark

*The declaration of conformity is valid in connection  
with the release technical document  
MDR-TCF-004*

*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-004-08

## 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 GOWN

Model: SQ-G5001 (XXL, XL, L, M, S)

SQ-G6001 (XXL, XL, L, M, S)

EMDN: T020401

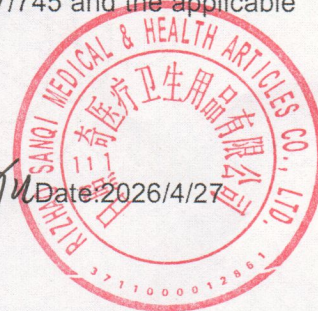
Basic UDI: 69563824surgicalgown9G

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