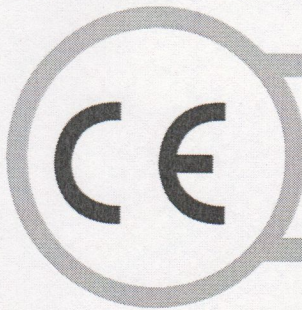




DECLARATION OF CONFORMITY

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

Remark

*The declaration of conformity is valid in connection
with the release technical document
MDR-TCF-003*

*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-003-08

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 isolation gown

Model: SQ-I1001 (XXL, XL, L, M, S); SQ-I2001 (XXL,
XL, L, M, S); SQ-I3001 (XXL, XL, L, M, S); SQ-I4001
(XXL, XL, L, M, S)

EMDN: T0299

Basic UDI-DI: 69563824isolationgownEN

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



Position: GM

Place: Shandong/China