



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
EN455-1:2020+A2:2024
EN455-2:2024
EN455-3:2023
EN455-4:2009

Remark

*The declaration of conformity is valid in connection
with the release technical document
MDR-TCF-006*

*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-006-08

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: MEDICAL NITRILE GLOVE

Model: SQ-GL201

EMDN: T01020204

Basic UDI-DI: 69563824NitrileGloveW8

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