# 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**

## 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**

## 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

## Product Information

**Name:** Medical Latex Glove
**Model: SQ-GL301**
**EMDN:** T010201
**Basic UDI-DI: 69563824LatexGlove5N**
**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.

**Remark**

*The declaration of conformity is valid in connection with the release technical document MDR-TCF-007*

*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.*

Signature: Julia Yu Date: 2026/4/27

RIZHAO SANQI MEDICAL & HEALTH ARTICLES CO., LTD. 日照三奇医疗卫生用品有限公司 3711000012861

File No.: MDR-TCF-007-08

Position: GM

Place: Shandong/China