



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

BSI Group The Netherlands B.V.

John M.Keynesplein 9, 1066 EP  
Amsterdam, The Netherland

## Conformity Assessment

### Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

### Applicable Standards

EN 149:2001 + A1:2009

## Remark

*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.*

## Manufacturer

**Name:** RIZHAO SANQI MEDICAL & HEALTH ARTICLES CO., LTD.

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

## Product Information

**Name:** Particle Filtering Half Mask

### Model:

FFP1: 3Q0C3S,3Q0C3V,

FFP2: 9505H,9505HV,9505HC,9505HCV,  
3Q1C3S,3Q1C3V,3Q1C4S,3Q1C4V,

FFP3: 3Q2A3S,3Q2A3V.

**GMDN:** 35177

**Classification:** Class I

## 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:

Date:16 Feb, 2024

Name: Wang ChangShen

Position: General Manager

Place:Rizhao

