



# 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-00000247

## 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-002.*

*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: NINGBO EAST PACKAGING  
TECHNOLOGY CO.,LTD  
Address: NO.5000 AIRPORT ROAD,SHIQI  
STREET,HAISHU,NINGBO ZHEJIANG,CHINA  
SRN: CN-MF-000055579

## Product Information

Name: Disposable Nitrile Gloves  
Model: 9" Black, 9" White, 9" Blue, 9" Purple, 9" Pink, 12" Black, 12" White, 12" Blue, 12" Purple, 12" Pink  
EMDN: T010202  
Basic UDI-DI: 698014962DNGR7  
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:  Date:2026/06/01

Position:GM

Place:Ningbo/China