



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-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.

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 vinyl Examination Gloves
Model: 9" Clear, 9" Black, 9" Blue, 9" Purple, 9" Pink, 9" White, 12" Clear, 12" Black, 12" Blue, 12" Purple, 12" Pink, 12" White
EMDN: T010299
Basic UDI-DI: 698014962DvEGRC
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