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
ISO 15223-1: 2021/Amd1: 2025
ISO 10993-1: 2018
ISO 10993-5: 2009
ISO 10993-10: 2021
ISO 10993-23: 2021
EN ISO 20417: 2021
EN455-1:2020+A1: 2022
EN455-2:2015
EN455-3:2023
EN455-4:2009

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-T01020201-01.

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: Sword Xiantao Disposable Protective Products Factory
Address: Liukou Industrial Zone, Xiantao City, 433000, Hubei Province, China
SRN: CN-MF-000009766

Product Information

Name: Vinyl Examination Gloves
Model: 6315
EMDN: T01020201
GMDN: 47176
Basic UDI-DI: 6971631676315AJ
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

IMPORTER

Name: INTERACTION-CONNECT s.a.
Address: 296-298 Route de Longwy L-1940 Luxembourg, Luxembourg
ID: LU-IM-000051233

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: 2026.1.6

Position:GM Place: Xiantao/China