



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
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Netherlands
SRN: NL-AR-000000247

Conformity Assessment

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

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2023
EN 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

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: 2024.7.8

Position: GM

Place: Xiantao/China