



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-00000247

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
EN455-2:2015
EN455-3:2015
EN455-4:2009

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-T01020204-01.

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: Shanghai Jessubond International Co., Ltd.
Address: No.558 Gangye Road, Dagang Songjiang
Dist, Shanghai
201614, China
SRN:

Product Information

Name: Disposable Nitrile Gloves
Model: ABC-DG01
EMDN: T01020204
Basic UDI-DI: /
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: *Blair Ma* Date: 2025.01.06

Position: GM Place: Shanghai/China

