



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 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-T0299-02.

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

Hubei Lioncare Protective Products Co., Ltd

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Ave,Wuhan,Hubei,China,430077

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Mail: info@lioncare.net

SRN: CN-MF-000020615

Product Information

Name: DISPOSABLE MEDICAL COAT

Model: S403+S503,L103HL,L103KL

EMDN: T0299

Basic UDI-DI: 697426174S403S503JL

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: Luca Liu

Date:2022.11.30



Position: GM

Place: Hubei/China