



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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
EN 14126:2003

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-T0299-05.

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: Hubei Maiyue Non woven products Co.,Ltd.
Address: Factory buliding no.12-1,zhanpeng Road, zhongling Industrial park,pengchang town, xiantao City.

Product Information

Name: COVERALL
Model: S,M,L,XL,XXL,XXXL
EMDN: T0299
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:  Date: 2022.01.19

Position: GM

Place: Hubei/China

