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: 2016
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-BA-07.

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: Wuhan Youfu International Trade Co., Ltd
Address: Room 3, 18F, unit B, Building S-1, Kaile Guiyuan,No.108, Zhuodaoquan Road, Hongshan District,Wuhan City, Hubei Province, China

Product Information

Name: Disposable apron
Model: YF8001,8002
GMDN: 40503
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: Erina Date: 2021-09-09

Position: GM Place: Wuhan/China

WUHAN YOUFU INTERNATIONAL TRADE CO.,LTD 武汉友福国际贸易有限公司