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

Manufacturer

Name: FEIXI HONGWEI MEDICAL DEVICES CO., LTD

Address: 2nd Floor, Building 6, Junction of Chuangxin Ave and Changgu Rd, Economic Development Zone, Feixi County, Hefei City, Anhui, China

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
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Product Information

Name: DISPOSABLE ISOLATION GOWN
Model: PP Isolation gown; SMS Isolation gown; SMMS Isolation gown; SMMMS Isolation gown; Nonwoven Gown; PE Laminated Isolation gown; Patient Isolation gown; Visitor Gown; Scrub Suit; Patient Suit; CPE Gown
GMDN: 35492
Basic UDI-DI: 697491661ISOG0112T
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: 2021.8.23

Position: GM Place: Anhui/China

Remark

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

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Sungo global service

Authorized Signature (S)