



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
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-T04010101-01.*

*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

Address: 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

SRN: CN-MF-000033411

Product Information

Name: DISPOSABLE ISOLATION GOWN

Model: PP Isolation gown

Ref NUM:ISOGOG30001

GMDN: 35492

EMDN: T0399

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:

Position: GM

Place: Anhui/China



2024.04.19