

DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer:

Wuhan Youfu International Trade Co., Ltd.

Room 3, 18F, unit B, Building S-1, Kaile Guiyuan,
No.108, Zhuodaoquan Road, Hongshan District,
Wuhan City, Hubei Province, China

Trademark:

SRN:

NL-AR-000000121

European Representative:

Lotus NL B.V
Koningin Julianaplein 10, 1e Verd, 2595AA,
The Hague, Netherlands.
Medicines and Healthcare Products Regulatory Agency
Competent Authority NL (CIBG)

SRN:

Not available yet

Trade name:

Isolation gown (non-sterile)

Product Name:

Isolation gown (non-sterile)

Product code / Catalogue number:

YF- IG

Basic UDI:

Not available yet

Classification acc. to MDR Ax. VIII:

Class I, rule I

Applied Standard & Common Specification:

EN 13688:2013 EN ISO 14971:2012 EN 1041:2013
EN ISO 15223-1:2016 EN ISO 10993-10:2013
EN ISO 10993-1:2009/AC:2010 EN ISO 10993-5:2009

Conformity assessment procedure:

Annex II + Annex III of MDR

CE certificate No.:

N.A.

Name and ID of the Notified Body:

N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR), and the provision of the Regulation (EU) 2016/425 on personal protective equipment. All supporting documentations are retained under the premises of the manufacturer.

Signature:

General Manager



Wuhan, 22.11.2020