CE DECLARATION OF CONFORMITY CE

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:	Cpe gown (non-sterile)
Product Name:	Cpe gown (non-sterile)
Product code / Catalogue number:	YF- CG
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 YOUFU INTERNATIONAL TRADE CO.,LTD 武汉友福国际贸易有限公司

Wuhan, 22 11 2020