
Declaration of Conformity

Regarding Medical Device Regulation (EU) 2017/745

Manufacturer: First Global Enterprises Limited

Address: Suite2006, 20th Floor, 340 Queen's Road Central, Sheung Wan, Hong Kong

Authorized European Representative: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestraße 80 20537 Hamburg GERMANY

Medical Device:

-Model Name: Isolation Gown

-Type or size: PP type, PP+PE type, CPE type; Size including S, M, L, XL, XXL, XXXL
REF: 700030 700040 701040 701050 700510 700520 700521

-Classification: I Non-Sterile (According to Rule 1, Annex VIII, Chapter III of EU Medical Device Regulation (EU)2017/745)

-UMDNS Code: UMDNS 15-037 Gowns, Isolation

-Conformity Assessment Procedure: Annex II+III

We herewith declare in our own responsibility that the above mentioned product(s) meet(s) the provisions of the Regulation (EU) 2017/745 concerning medical devices. All supporting documentation is retained under the premises of the manufacturer.

DIRECTIVES

General Applicable Directives:

We confirm our product can meet the requirement of Medical Device Regulation and the following harmonized standards:

Standards applied:

ENISO13485:2016/ ENISO14971:2019/ ENISO15223-1:2016/ EN1041:2008/
ENISO10993-1:2018/ ENISO10993-5:2009/ ENISO10993-10:2013

Suite 2006, 20th Floor, 340 Queen's Road Central,
Sheung Wan, Hong Kong

(Place and date of issue of this certificate)*

2021.03.26



Victoria

(Signature and title of authorized person)*