

EU DECLARATION OF CONFORMITY

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

Manufacturer: Aimmax Medical Products Co.,Ltd.
53 Hanjiang Avenue,Chadian Town,Yunyang District,
Shiyan,Hubei Province.

SRN: CN-MF-000010875

European Representative: Caretechion GmbH
Niederrheinstr 71, 40474 Duesseldorf, Germany

SRN: DE-AR-000005946

Product name: Isolation Gown

Size: XS, S, M, L, XL, XXL, XXXL, XXXXL

Basic UDI-DI: 697321034isolationgown4S

Classification acc. to MDR Ax. VIII: Class I, rule 1

Applied Standard & Common Specification: EN ISO 13485:2016 / EN ISO 14971: 2019
ISO10993-1:2018 / EN ISO10993-5:2009
EN ISO 10993-10:2013 / EN ISO 15223-1:2016

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). All supporting documentations are retained under the premises of the manufacturer.

Signature:

Wang Jun


Date:

2021-08-08

Position:

General Manager

Place:

Shiyan, Hubei