

Declaration of Conformity

Regarding Medical Device Regulation(EU) 2017/745

Manufacturer:

Name: Hygeia Medical Co. Ltd.

Address: Flat 10H, Hechuan Tower, No.2016 Yishan Road, 201103 Shanghai, P.R. China

Tel.: +86-21-61280541 Fax: +86-21-61280540

European Representative:

Name: Shanghai International Holding Corp.GmbH (Europe)

Address: Eiffestrasse 80,20537 Hamburg Germany

Tel: +49-40-2513175

Product: Disposable Isolation gown

Size: S,M,L,XL,XXL

Article Nr: ME-4016HYG

Classification: I

Rule: According to Rule 1,Annex VIII, Regulation(EU)2017/45

We,Hygeia Medical as the manufacturer of following medical devices, takes sole responsibility and declares conformity with the applicable provisions of Medical Device Regulation(EU)2017/745 concerning medical devices and the following harmonized standards.

EN ISO 14971:2012

EN ISO15223-1:2016

EN 1041: 2008+A1:2013

EN ISO 10993-1:2018

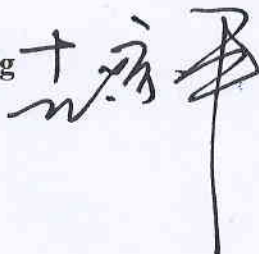
EN ISO 10993-5:2009

EN ISO 10993-10:2013

DIN ISO 13485

Signature: Zhao Jingping

Title: General Manager



Date: 2021.8.1