



ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

Product Information:

Name: Disposable gown

Model: Standard

GMDN: 58390

Basic UDI-DI: /

Classification: Class I

Manufacturer

Name: Shanghai HBM Healthcare, Inc.

Address: #1508-1509, No. 211, Golden Port Road, Pudong, Shanghai, China.

EU Representative:

HBM Medical

Address: Coliemore House, Coliemore Road, Dalkey, Co Dublin, Ireland

Conformity Assessment

Conformity Assessment Produce

Annex II+III of Regulation (EU) 2017/745

Applicable Standards:

EN ISO 14971: 2012, EN ISO 15223-1: 2016, EN 1041: 2008+A1:2013, ISO 10993-1:2018

EN ISO 10993-5:2018, EN ISO 10993-10:2018

Declaration

We herewith declare that the above mentioned Products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standard above.

Remark:


The declaration of conformity is valid in connection with the release technical documents CE/MDR/HBM-001

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of conformity is exclusively under the sole responsibility of the manufacturer.


Yuhong CHEN
Vice General Manager, Medical Greater China
TÜV Rheinland (China) Ltd


Signature:



Position: General Manager

Date: AUG. 30, 2021

