



WUHAN TOPMED TRADING CO.,LTD

ADD:D-1905,Future City Building,South of Luoshi Road No.147,

Hongshan District, Wuhan,China,430070

Tel: 86-27-87861070 Fax: 86-27-87861011 Website: www.topmeddisposable.com

DECLARATION OF CONFIRMITY

Manufacturer: Wuhan Topmed Trading Co., Ltd.
1904-1905, Block D, Future City
No. 147 South of Luoshi Road
Hongshan District
430070 Wuhan, Hubei
People's Republic of China

European Representative: Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany

Products: Non sterile Face mask
Non sterile Isolation gown
Non sterile Clip cap

Classification: (Annex V) Class I

We herewith declare the above mentioned products meet the transposition into national law, the provision of the following EC council Directives and standards. All supporting documents are retained under the premises of the manufacturer.

Medical Device Directive: Council Directive 93/42/EEC

Conformity Assessment Route: Annex V

Applied Standards: EN ISO 13485:2016+ AC: 2016
Medical Devices – Quality managements systems – Requirements for regulatory purposes.

Certificate number: Q6 074142 0006

Valid from: 10.04.2019

Valid until: 11.04.2020

Signature: ^{For and on behalf of}
武汉拓迈贸易有限公司
WUHAN TOPMED TRADING CO., LTD

Name: Rong Zhu

Position: CEO
Authorized signature