

# Declaration of Conformity

Manufacturer:

**Nanjing Universal Medical Equipment Co., Ltd.**

288 Qinhuai Avenue, Yongyang Street, Lishui District, Nanjing, China

Authorized EU-Representative

**MB Global Service AB**

Prastgatan 68, 111 29 Stockholm, Sweden

Email: Info@mbgls.com

We, the manufacturer, hereby declare the products listed below,

***Disposable Medical Nitrile Examination Gloves (Non-Sterile) GMDN Code 56286***

***Product Referenece No.:UN-U001***

Meet the provision of Directive 2017/745 which apply to them. The number of relevant technical document is CE-N001.

The medical device has been classified as Class I medical device according to Rule I of Annex VII of the Directive 2017/745.

The statement of this declaration of conformity is issued under the sole responsibility of the manufacturer. All non-sterile gloves supplied by the manufacturer are covered by the declaration.

According to the procedure relating to the EC Declaration of Conformity setting out in Annex IV of Directive 2017/745.



List of Harmonised standards,

*EN 455-1:2000 Medical gloves for single use. Requirements and testing for freedom from holes*

*EN455-2:2015 Medical gloves for single use. Requirements and testing for physical properties*

*EN455-3: 2015 Medical gloves for single use. Requirements and testing for biological evaluation*

*EN455-4:2009 Requirements and testing for shelf life determination*

*EN 980:2008 Symbols for use in the labelling of medical devices*

Signature



Name (PRINTING) Jia Xiaolin

Position: Legal representative

Issuing Date: November 3rd, 2021

Issuing at: Nanjing,China

Nanjing Universal Medical Equipment Co., Ltd.