

Technical Documentation No.: CLW/MQMS30803

## EC Declaration of Conformity

**Manufacturer:**

*Suzhou Colour-way New Material Co., Ltd.  
No. 20, Anmin Road, Huangdai Town,  
Xiangcheng District, 215152 Suzhou City,  
Jiangsu Province, PEOPLE'S REPUBLIC  
OF CHINA*

**whose single Authorized EU-Representative:**

*Name: Shanghai International Holding Corp.  
GmbH (Europe)  
Add: Eiffestraße 80, 20537 Hamburg, Germany  
DIMDI Code: DE/0000040627  
E-mail: shholding@hotmail.com*

We, the manufacturer, herewith declare that the products:

*Examination Gloves*

Model: Textured surface / Smooth surface; Powdered / Powder-free

Size: XS, S, M, L, XL

meet the provisions of Medical Device Regulation (EU) 2017/745 which apply to them.

The medical device has been assigned to class I according to Appendix VIII of the Regulation (EU) 2017/745. It bears the mark



following the conformity assessment procedures relating to the EC Declaration of Conformity set out in Annex IX of Regulation (EU) 2017/745.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration.

The product identified above complies with the essential requirements of the above EC Directives by meeting the following standards: It bears the mark

**EN 455-1: 2000; EN 455-2:2015; EN 455-3:2000; EN ISO 14971:2012  
EN ISO 10993-1:2018; EN ISO 10993-5:2009; EN ISO 10993-10:2013;  
EN ISO 15223-1:2016; EN 1041:2006+A1:2013**

The above mentioned declaration of conformity is exclusively under the responsibility of

*Suzhou Colour-way New Material Co., Ltd.  
No. 20, Anmin Road, Huangdai Town, Xiangcheng District, 215152 Suzhou City, Jiangsu  
Province, PEOPLE'S REPUBLIC OF CHINA*

*Suzhou, March 28, 2020*

Place, date

*Xu Yongning*  
Legally binding signature, PC

Position: General manager

