

EC Declaration of Conformity

1. Products

No.	Products	UMDNS Code	Classification Rules	Classification
1	Medical face Mask Type I ^a	12458	Rule 1	I
2	Medical face Mask Type II			
3	Medical face Mask Type IIR			

2. Manufacturer

Name: Winner Medical Co., Ltd.

Address: Winner Industrial Park, No.660 Bulong Road, Longhua District, 518109 Shenzhen, CHINA

3. EC- Representative

Name: Shanghai International Holding Corp, GmbH (Europe)

Address: Eiffestraße 80, 20537 Hamburg, Germany

4. Notified Body (Applicable for Class I sterile and Class IIa products only)

Name: TÜV SÜD Product Service GmbH

Identification No.: 0123

Address: Zertifizierstelle, Ridlerstraße 65, 80339 München, GERMANY

5. Statement

We hereby declare that above mentioned products with CE marking meet the provisions of Medical Device Directive 93/42/EEC and related harmonized standards. We take full responsibility for all content in this declaration.

6. Applicable Harmonized Standards

EN ISO 13485:2016, EN 1041:2008, ISO 2859-1:1999, EN 14683:2019, ISO 14644-1:2015, EN ISO 14971:2012, ISO 14698-1:2003, ISO 14698-2:2003, ISO 10993-1:2018, ISO 10993-10:2010, EN ISO 10993-5:2009, EN ISO 10993-12:2012, EN ISO 15223-1:2016, ISO 15223-2:2010, EU/EC MEDDEV 2.7/1

7. Conformity Assessment Procedures

EC declaration of conformity (Annex VII) of Council directive 93/42/EEC concerning medical devices for Class I (Non-sterile) medical devices.

EC declaration of conformity (Annex VII) + Production quality assurance (Annex V) of Council directive 93/42/EEC concerning medical devices for Class I (Sterile) medical devices.

2020-04-30

Date (YYYY-MM-DD)



Xiaomeng Yang

Signature (Xiaomeng Yang/Management Representative)