

EC Declaration of Conformity**1. Products**

No.	Products	UMDNS Code	Classification Rules	Classification	REF
1	Surgical Face Mask Ear Loop, Type IIR	12458	Rule 1	I	1000010123
2	Surgical Face Mask Tie-on, Type IIR	12458	Rule 1	I	1000010124

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. 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.

5. Applicable 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 15223-1:2016, ISO 15223-2:2010, EU/EC MEDDEV 2.7/1

6. 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.

Signature (Xu Jing, Registration and quality system Manager)



2020.11.11

Date (YYY-MM-DD)

