

## EU Declaration of Conformity

### 1. Products

No.	General Device Group	Product	Rule	Risk Class	Basic UDI-DI
1	(non-sterile) Face Mask	Medical Face Mask with tie (Type I)	Rule 1	Class I non-sterile	694109403786FM
2		Medical Face Mask with tie (Type II)			694109403787FP
3		Surgical Face Mask with tie (Type IIR)			694109403788FR
4		Medical Face Mask with earloop (Type I)			694109403789FT
5		Medical Face Mask with earloop (Type II)			694109403790FC
6		Surgical Face Mask with earloop (Type IIR)			694109403791FE
7		Medical Face Mask with soft earloop (Type I)			694109403792FG
8		Medical Face Mask with soft earloop (Type II)			694109403793FJ
9		Surgical Face Mask with soft earloop(Type IIR)			694109403794FL

### 2. Manufacturer

Name: Winner Medical Co., Ltd.  
Address: Winner Industrial Park, No.660 Bulong Road, Longhua District, 518109  
Shenzhen, CHINA  
SRN Number: CN-MF-000005692

### 3. Authorised Representative

Name: Shanghai International Holding Corp, GmbH (Europe)  
Address: Eiffestraße 80, 20537 Hamburg, Germany

### 4. Statement

We hereby declare that the above mentioned products with CE marking meet the provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council .The CE marking is subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

### 5. Conformity Assessment Procedure

EU declaration of conformity (Article 19) + technical documentation (Annexes II and III) of Regulation (EU) 2017/745 concerning medical device for Class I (Non-sterile) medical device.

For and on behalf of Winner Medical Co.,Ltd.

*Xiaomeng, Yang*

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Xiaomeng, Yang  
Management Representative  
Shenzhen, China.

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