

## Declaration of Conformity

**Manufacturer:** RFX + CARE Manufacturing Co., Ltd...

**Address:** 7 Lanjiang Road, Yuecheng District, Shaoxing, P. R. China

**EC-Representative:** RFX+Care International A/S

**Address:** Bakkegaardsvej 408, 3050 Humlebaek, Denmark

**Product Name:** Face Mask

**Specification:** 9.5cm\*17.5cm-3ply

**UMDNS Code:** 16366

**Classification:** Class I, rule1

**Conformity Assessment Route:** Annex VII

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

RFX + CARE Manufacturing Co., Ltd. is exclusively responsible for the declaration of conformity.

### Medical Device Directives

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

Notified Body: TÜV SÜD Product Service GmbH,  
Ridlerstrasse 65, 80339 München, Germany

NB Identification number: 0123  
(QMS) Certificate(s): Q5 067759 0027 Rev.01  
Expire date of the Certificate: 2022-10-31  
Start of CE Marking: 2014-10  
Place, Date of Issue: Shaoxing, 2018-09-17

General Manager (Signature): \_\_\_\_\_

Date: 2018-09-17

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RFX/ JCQ-CE-026-01 Declaration of conformity(face mask)	02	2018-09-17	1 / 1





Product Service

# Certificate

No. Q5 067759 0027 Rev. 01

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** RFX+CARE Manufacturing Co., Ltd.  
7 Lanjiang Road, Yuecheng District, 312000 Shaoxing, Zhejiang,  
PEOPLE'S REPUBLIC OF CHINA

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