

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

File No/File Name	Edition	Effective Date	Pages	
RFX/ JCQ-CE-026-01 Declaration of conformity(face mask)	02	2018-09-17	1 / 1	







Certificate

No. Q5 067759 0027 Rev. 01

Holder of Certificate: RFX+CARE Manufacturing Co., Ltd.

7 Lanjiang Road Yuecheng District

312000 Shaoxing, Zhejiang PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design, Development, Production and Distribution of First Aid Kits, Plasters, Condoms, Safety Kits and Silicone Foam Dressing

Production and Distribution of Bandage, Gauze Swabs, Non woven Swabs, Gauze Balls, Non woven Balls, Cotton Rolls, Shoe Covers, Face Masks, Emergency Blankets, Sterile Burn Dressing, Sterile Wound Dressing, Relieve Burn Gels, Alcohol Prep Pads, Sterile Single Use Wound Cleansing Swabs, Adhesive Strips/Tapes, Examination Gloves, Sterile Hydrocolloid Dressings, Sterile Single Use Cleaning Tubes,

Thermometer, Warmers, Cold Packs, Hot Packs,
Cold /Hot Pack, Sterile Eye Pads, Tweezers,
Bandage Scissors, Respiratory Sheet, Wash Swabs,
Blister Plasters, Sterile Non Woven Compress,
Cleansing Swab and Tube, Alcohol Swabs,
Instant Cold Packs, Wound Skin Closure Strips,
Sterile Absorbent Pad, Bee Plasters, Sterile Cotton Balls,
Tick Removers, Forehead Thermometers, Eye Wash,
Sickness Bands, Sports Supports and Foot Care Cushion

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1952701

Valid from: 2020-01-29 Valid until: 2022-10-31

Date, 2020-01-29

Christoph Dicks

Head of Certification/Notified Body





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