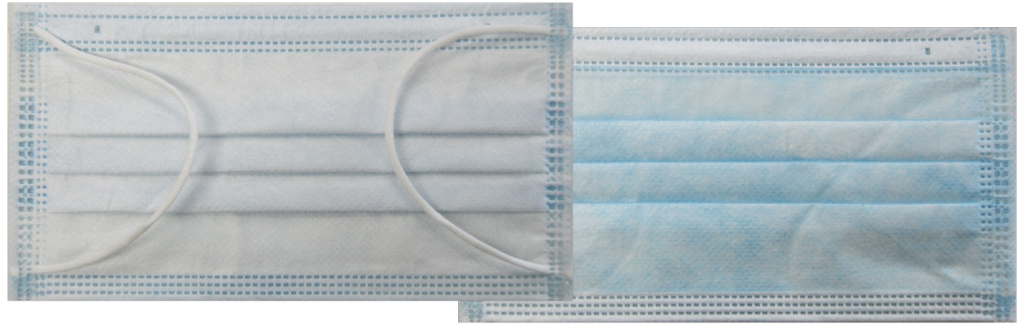


# Face mask

## Technical data sheet


**ID name:** Face mask

**Intended use:**

Prevention towards spread of infectious breath, cough and sneeze. Protection against inhalation of airborne particles such as dust, pollen and transmittable bacteria and vira.

**Instruction for use:**

1. Wash your hands thoroughly before AND after wearing.
2. Take hold of the mask at the upper edge, where the nasal clamp is felt and with the blue side facing outwards.
3. Place the nasal clamp over the nasal ridge and apply pressure to fasten the mask.
4. Holding the nasal clamp gently pull the lower edge of the mask downwards in order to expand the mask.
5. Place the earstrings firmly around ears.
6. Gently press the nasal bridge clamp around the nose to ensure a tight fit and adhesion.
7. Spread and unfold until it covers the chin completely, leaving no gaps between the mask cheeks and chin.
8. Dispose in closed bin

**Warning:**

Single use only. Do not use if the mask is dirty or broken. Keep away from small children. Non sterile.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

**CE Class:** I Type IIR

**Product properties:**

Size: 17.5x9.5cm

Material:

Non-woven fabrics PP Spunbonded + Melt Blown + PP Spunbonded

Nasal bridge clamp: PE

Ear string: Polyethylene glycol terephthalate 86%+polyurethane 14%

Latex free

Bacteria filter effect (BFE)  $\geq 98\%$

**Storage:**

Should be stored in a cool dry environment for best result of product performance. Keep away from light and heat.

**Shelf life:**

5 Years

**Legal manufacturer:**

RFX+CARE Manufacturing Co., Ltd. 7 Lanjiang Road, Yuecheng District, Shaoxing, Zhejiang, China 312000.

**EC-Representative:**

RFX+Care International A/S. Bakkegaardsvej 408, 3050 Humlebaek, Denmark

**Certificates TÜV SÜD:**

EN ISO 13485:2016

**Reference reports and certificates:**

Annex 1 ISO13485:2016 Certificate

Annex 2 Bacteria filter effect (BFE) tested following EN 14683

Annex 3 Synthetic Blood Penetration EN 14683:2019

Annex 4 Cytotoxicity test, skin irritation test, delayed-type hypersensitivity (Maximization test)

**Packaged Art no.**

FA200-565931 –	50 pcs in GRAID Box
FA200-565924 –	10 pcs in GRAID Box
FA200-565917 –	5 pcs in GRAID Box
FA200-565900 –	3 pcs in GRAID Box
FA200-565986 –	1 pcs flow wrapped 2 labels
FA200-566129 –	1 pc flow wrapped 1 label
FA200-565993 –	50 pc bulk in

**Product description**

Table 1 — Performance requirements for medical face masks

Test	Type I <sup>a</sup>	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	$\geq 95$	$\geq 98$	$\geq 98$
Differential pressure (Pa/cm <sup>2</sup> )	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	$\geq 16,0$
Microbial cleanliness (cfu/g)	$\leq 30$	$\leq 30$	$\leq 30$

<sup>a</sup> Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

EC-Representative: RFX+Care International A/S • Bakkegaardsvej 408 • 3050 Humlebaek • Denmark



Re. Face mask information / documentation

Humblebaek 27..03.2020

### Does a face mask help in a coronavirus situation?

This is the big question. There is a lot of talk about this. As the virus is still new and many questions still stand unanswered mask do help in the fight against coronavirus. Our mask is Medical Class I type IIR mask to prevent passing on bacteria and virus. Mask will help us in the fight against the virus. It is essential that we do not pass it on to one another if we want to stop this pandemic.

- **Facts about RFX+Care face mask:**

Face mask with soft and strong ear elastic and nose clamp ensuring a good fit. The mask has high bacterial filtration. The mask is recommended for use by healthcare professionals to reduce cross-contamination. Protecting against and minimizing risk of infection.

- **CE approved:** CE marked in accordance with EU Directive on Medical Devices 93/42 / EEC, Annex V.3 & VII Class I rule I Type IIR approved in accordance with EN 14683: 2019.
- (See enclosed TDS, FSC, ISO EN13485 cert.)

- **Test:** Type IIR approved in accordance with EN 14683: 2019. Bacteria filter effect (BFE) tested and approved in accordance with tests for Class I Type IIR. We guarantee BFE  $\geq 98\%$  and splash resistance. Biocompatibility tested and approved in accordance with ISO10993. (See enclosed test reports from Nelson Labs)

- See on following page photos from our production site
- See below explanatory table

Table 1 — Performance requirements for medical face masks

Test	Type I *	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	$\geq 95$	$\geq 98$	$\geq 98$
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\* Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

For any further questions feel free to send an e-mail to [info@rfx-care.com](mailto:info@rfx-care.com)

Camilla Oppenheim  
Compliance Manager

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### RFX-Care International A/S

Bakkegaardsvej 408, 3050 Humlebaek, Denmark Tel: 45 76 90 20, Fax: 45 76 02 98  
[www.rfx-care.com](http://www.rfx-care.com)- e-mail: [info@rfx-care.com](mailto:info@rfx-care.com)



**Mask production in Cleanroom**

RFX+CARE Manufacturing Co., Ltd.

No. 7 Lanjiang Road, Yuecheng District,

Shaoxing, Zhejiang, P.R.China 312000



**RFX-Care International A/S**

Bakkegaardsvej 408, 3050 Humlebaek, Denmark Tel: 45 76 90 20, Fax: 45 76 02 98  
www.rfx-care.com- e-mail: info@rfx-care.com



## Free Sales Certificate

The Danish Health and Medicines Authority hereby certifies that

**RFX-Care International A/S**  
**Bakkegaardsvej 408,**  
**3050 Humlebæk**

is the Authorized representative in the European Union for the medical devices specified in the attached list which are manufactured and CE-marked by

**RFX+CARE Manufacturing Co. Ltd ,**  
**No. 7 Lanjiang Road, Yuecheng District,**  
**Shaoxing, Zhejiang, P.R.China 312000**

Medical devices which are CE marked in conformity with Directive 93/42/EEC meet the essential requirements for safety and performance. They may therefore be marketed in Denmark and exported freely without any approval from the Danish Health and Medicines Authority.



Valid from: 14 August 2019  
Valid Until: 31 October 2020

**Cecilie Sommer**





**Components information for first aid kit /Safety kit 09/08/2019**

S/N	Name of Product	Types/Sizes/Models	Classification	Rule of classification	Remark
1.	Sterile Bandage	6x8cm /8x10cm/10x12cm/10x16cm/17x17cm/ etc.	I sterile	Rule 4	
2.	Sterile non-woven burn dressing	40x60cm/ 60x80cm/ etc.	I sterile	Rule 4	
3.	PBT bandage	8cm x 4m/ 6cm x 4m/ 8cm x 3m/ etc.	I	Rule 4	
4.	Triangular bandage	96x96x136cm/ 90x90x127cm/ etc.	I	Rule 4	
5.	Adhesive tape	1.25cm x 5m/ 2.5cm x 5m/ etc.	I	Rule 4	
6.	Adhesiv bandage/ Plaster	Round shape: $\phi$ 2.5 cm/ etc. Rectangle shape: 1.9 x 7.2 cm, 1.9 x 5.6 cm, 1.9 x 7.7 cm 10 x 6cm/ etc. Bandage shape: 1.25cm x 5m/10m, 2.5cm x 5m/10m, 5cmx 5m/10m, 7.5cm x 5m/10m, 10cm x 5m/10m, 15 x 5m/10m.	I sterile	Rule 4	
7.	Wound skin Closure Strip	6mm x 7.5cm	I sterile	Rule 4	
8.	Examination Glove	S/M/L, etc	I	Rule 1	
9.	Instant cold pack	80g/100g/160g/220g/300g	IIa	Rule 9	
10.	Sterile Hydrocolloid dressing/Blister plaster	5.5cm x 3.7cm 6.9cm x 4.4cm 4.8x1.7cm, 5cm x5cm, 3cm x 3cm/etc	IIa	Rule 4	
11.	Sterile Non-woven compress	5x5cm, 7x7cm, 10x10cm/ etc	I sterile	Rule 4	
12.	Burn gel	3.5g, 10cmx10cm/ etc	IIa	Rule 4	
13.	Alcohol swab	3 x 3 cm, 15 x 15cm	I sterile	Rule 1	
14.	Sterile Non-woven swab	7 x 7.5cm, 7 x 7.5cm-2p, 5.6cm x 7.2 cm, etc.	I sterile	Rule 4	





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15.	Cleansing tube	15ml, 20ml, 30ml, 500ml	IIa	Rule 4	
16.	Digital Thermometer	MT-201	IIa	Rule 10	
17.	Face mask	9.5x17.5cm-3ply	I	Rule 1	
18.	Emergency blanket	160x210 cm, 130x210cm/ etc	I	Rule 1	
19.	Warmers	90x55mm	IIa	Rule 9	
20.	Bandage Scissor	12.7cm, 9cm, 19cm/ etc	I	Rule 1	
21.	Tweezer	8.8cm/ 10.7cm/ etc.	I	Rule 1	
22.	Respiratory Sheet	20x32cm	I	Rule 1	
23.	Sterile absorbent pad	12.5x22.5cm/5.6cm x 7.2 cm	I sterile	Rule 4	
24.	Condom	49mm, 52mm, 55mm.	IIb	Rule 14	
25.	Sterile Gauze swab	5cmx5cm, 7.5cmx7.5cm, 10cmx10cm	I sterile	Rule 4	
26.	Bee plaster	38x38mm	I	Rule 4	
27.	Cotton Balls /Sterile Cotton Balls	0.5g	I/II sterile	Rule 4	
28.	Tick remover	S, M, 9.5cm/ etc	I	Rule 1	
29.	Forehead thermometer /URGO Forehead thermometer	35-40°C	I	Rule 1	
30.	Eye Wash	5ml, 10ml, 15ml, 20ml, 30ml, 100ml, 250ml, 500ml, 1000ml	I sterile	Rule 5	
31.	Sickness Band	5x3cm/pair	I	Rule 1	
32.	Silicone Foam Dressing	Standard: without border-- 5 x 5cm, 7.5x 7.5cm, 10x10cm, 12.5 x12.5cm, 15 x 15cm, 15x18cm, 15x20cm, 14x21cm, 14x22cm; with border--7.5x7.5cm, 10x10cm, 12.5x12.5cm, 15x15cm, 15x18cm, 12.5x20cm, 18x18cm, 18x20cm, 22.5x22.5cm; Extra thin: without border--6x8.5cm, 10x10cm, 15x15cm, 20x50cm; with border--4x5cm, 5x12.5cm, 7.5x7.5cm, 10x10cm, 15x15cm.	IIb	Rule 4	



**LÆGEMIDDELSTYRELSEN**  
DANISH MEDICINES AGENCY





# 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.

<b>Report No.:</b>	SH1952701
<b>Valid from:</b>	2020-01-29
<b>Valid until:</b>	2022-10-31

**Date,** 2020-01-29

Christoph Dicks  
Head of Certification/Notified Body

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ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFIKAT ♦ CERTIFICADO ♦ CERTIFICAT



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

A4 / 07.17



## Synthetic Blood Penetration Resistance Final Report

Test Article: D20108  
Study Number: 1274551-S01  
Study Received Date: 06 Mar 2020  
Testing Facility: Nelson Laboratories, LLC  
6280 S. Redwood Rd.  
Salt Lake City, UT 84123 U.S.A.  
Test Procedure(s): Standard Test Protocol (STP) Number: STP0012 Rev 09  
Deviation(s): None

**Summary:** This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of  $21 \pm 5^\circ\text{C}$  and a relative humidity of  $85 \pm 10\%$ . Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested: 32  
Number of Test Articles Passed: 31  
Test Side: Outside  
Pre-Conditioning: Minimum of 4 hours at  $21 \pm 5^\circ\text{C}$  and  $85 \pm 5\%$  relative humidity (RH)  
Test Conditions:  $22.7^\circ\text{C}$  and 21% RH

**Results:** Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when  $\geq 29$  of 32 test articles show passing results.

Test Pressure: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-18, 20-32	None Seen
19	Yes



Study Director

James W. Luskin



*20 MAR 2020*  
Study Completion Date



1274551-S01

801-290-7500 | [nelsonlabs.com](http://nelsonlabs.com) | [sales@nelsonlabs.com](mailto:sales@nelsonlabs.com)

hcb

FRT0012-0002 Rev 13

Page 1 of 1

## Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article: D20108 / 45177(SDJF)  
medical face mask  
Study Number: 1281819-S01  
Study Received Date: 27 Mar 2020  
Testing Facility: Nelson Laboratories, LLC  
6280 S. Redwood Rd.  
Salt Lake City, UT 84123 U.S.A.  
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 18  
Deviation(s): None

**Summary:** The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at  $1.7 - 3.0 \times 10^3$  colony forming units (CFU) with a mean particle size (MPS) of  $3.0 \pm 0.3 \mu\text{m}$ . The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Inside  
BFE Test Area:  $\sim 40 \text{ cm}^2$   
BFE Flow Rate: 28.3 Liters per minute (L/min)  
Delta P Flow Rate: 8 Liters per minute (L/min)  
Conditioning Parameters:  $85 \pm 5\%$  relative humidity (RH) and  $21 \pm 5^\circ\text{C}$  for a minimum of 4 hours  
Test Article Dimensions:  $\sim 170 \text{ mm} \times \sim 158 \text{ mm}$   
Positive Control Average:  $2.5 \times 10^3$  CFU  
Negative Monitor Count:  $< 1$  CFU  
MPS:  $3.2 \mu\text{m}$



*Trang Luong for*  
Study Director James W. Luskin

*04 Apr 2020*  
Study Completion Date



1281819-S01

**Results:**

Test Article Number	Percent BFE (%)
1	99.9
2	>99.9
3	>99.9
4	99.9
5	>99.9

Test Article Number	Delta P (mm H <sub>2</sub> O/cm <sup>2</sup> )	Delta P (Pa/cm <sup>2</sup> )
1	4.5	44.0
2	4.3	41.7
3	4.2	41.6
4	4.8	47.3
5	4.4	42.8

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} \times 100$$

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request