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%+polyurethane14%
Latex free
Bacteria filter effect (BFE) ≥98%

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

Shelf life:
3 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 hyper sensitivity (Maximization test

Packaged Art no.	Product description
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

Table 1 — Performance requirements for medical face masks

Test	Type I [a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm^2)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

[a] 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.

Re. Face mask information / documentation

Humlebaek 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 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 ≥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

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For any further questions feel free to send an e-mail to info@rfx-care.com

Camilla Oppenhejm
Compliance Manager

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

Mask production in Cleanroom

RFX+CARE Manufacturing Co., Ltd.

No. 7 Lanjiang Road, Yuecheng District,

Shaoxing, Zhejiang, P.R.China 312000

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

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 form the Danish Health and Medicines Authority.

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

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

Cecilie Sommer

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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: ϕ 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/ I 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, 22.5x225.5cm; Extra thin: without border--6x8.5cm, 10x10cm, 15x15cm, 20x50cm; with border--4x5cm, 5x12.5cm, 7.5x7.5cm, 10x10cm, 15x15cm.	IIb	Rule 4	

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

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:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

Nelson Labs
A Sotera Health company

Sponsor:
Zhengyan Zhu
RFX+CARE Manufacturing Co., Ltd.
No. 7 Lanjiang Road
Yuecheng District
Shaoxing, 312000
CHINA

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 ± 5°C and a relative humidity of 85 ± 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 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	22.7°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 ≥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

Nelson Labs.
A Sotera Health company

Sponsor:
Zhengyan Zhu
RFX+CARE Manufacturing Co., Ltd.
No. 7 Lanjiang Road
Yuecheng District
Shaoxing, 312000
CHINA

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 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. 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:	~40 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 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~170 mm x ~158 mm
Positive Control Average:	2.5 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.2 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Study Director: Trang Thuong for James W. Luskin — Study Completion Date: 04Apr2020

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_2O/cm^2)	Delta P (Pa/cm^2)
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:

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

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request