

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 virus.

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) ≥ 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 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 ^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.

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



Re. Face mask information / documentation

Humblebaek 11.11.2020

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 $\geq 98\%$ 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

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

Camilla Oppenheim
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



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



Product Service

Certificate

No. Q5 067759 0027 Rev. 02

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,
Isolation Gown, Coverall, Silver Plaster

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:Q5_067759_0027_Rev_02

Report No.: SH2052701
Valid from: 2020-11-12
Valid until: 2023-10-31

Date, 2020-11-12

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 067759 0027 Rev. 02

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

RFX+CARE Manufacturing Co., Ltd.
21 Caojing Road, Yuecheng District, 312000 Shaoxing, Zhejiang,
PEOPLE'S REPUBLIC OF CHINA

ZERTIFIKAT ♦ CERTIFICATE ♦ 認證證書 ♦ CERTIFICADO ♦ CERTIFICAT



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: 20 October 2020
Valid Until: 20 October 2022

Natasha Madsen
Natasha Helleberg Madsen



LÆGEMIDDELSTYRELSEN

DANISH MEDICINES AGENCY



Components information for first aid kit /Safety kit 30/09/2020

| 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, 9x14.5cm-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. | Sterile Gauze swab | 5cmx5cm, 7.5cmx7.5cm, 10cmx10cm | I sterile | Rule 4 | |
| 25. | Bee plaster | 38x38mm | I | Rule 4 | |
| 26. | Cotton Balls /Sterile Cotton Balls | 0.5g | I/ I sterile | Rule 4 | |
| 27. | Tick remover | S, M, 9.5cm/ etc | I | Rule 1 | |
| 28. | Forehead thermometer /URGO Forehead thermometer | 35-40°C | I | Rule 1 | |
| 29. | Eye Wash | 5ml, 10ml, 15ml, 20ml, 30ml, 100ml, 250ml, 500ml, 1000ml | I sterile | Rule 5 | |
| 30. | Sickness Band | 5x3cm/pair | I | Rule 1 | |
| 31. | Sports supports | Shoulder support, back support, ankle support, knee support, plam support, elbow support, neck support, calf support /etc | I | Rule 1 | |
| 32. | Foot care cushion | 63x27mm, 37x25mm, 15x15mm, Ø3.5cm / etc | I | Rule 1 | |
| 33. | Kinesiology bandage | 5cm x5m, 5x12.5cm, 5x25cm | I | Rule 1 | |



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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°C and 21% RH

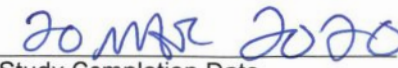
Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥ 29 of 32 test articles show passing results.

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


Study Completion Date

1274551-S01

801-290-7500 | nelsonlabs.com | 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: $2.5 \times 10^3 \text{ CFU}$
Negative Monitor Count: $< 1 \text{ CFU}$
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 ₂ O/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:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request