Humlebaek 17.03.2020

Re. Face mask information

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 used in hospital operation rooms to prevent passing on bacteria and virus. As far as we know you can be a carrier of the decease without having clear symptoms. This means that a mask WILL help us the coronavirus fight. It is just as important no passing the virus on as conceiving it !!

Facts about wearing a mask:

Wear a facemask if you are sick

- **If you are sick:** You should wear a facemask when you are around other people (e.g., sharing a room or vehicle) and before you enter a healthcare provider's office. If you are not able to wear a facemask (for example, because it causes trouble breathing), then you should do your best to cover your coughs and sneezes, and people who are caring for you should wear a facemask if they enter your room.
- **If you are NOT sick:** You do not need to wear a facemask unless you are caring for someone who is sick (and they are not able to wear a facemask). Facemasks may be in short supply and they should be saved for caregivers.

  CDC (https://www.cdc.gov/coronavirus/2019-ncov/about/prevention.html**)**

- **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 V11, Class 1 Type II approved in accordance with EN 14683: 2014. (See enclosed FSC and ISO EN13485 cert..)

- **Test:** Bacteria filter effect (BFE) tested in accordance with tests and requirements of the EU Medical Device Directive 93/42 / EEC, Annex VII, class 1 Type II approved in accordance with EN 14683: 2014. We guarantee BFE ≥98%. (See enclosed test report from Nelson Labs)

- Class I medical devices do not get an EC cert. issued. See statement, explanation about classification by Anette Sjögren incl. Bios.

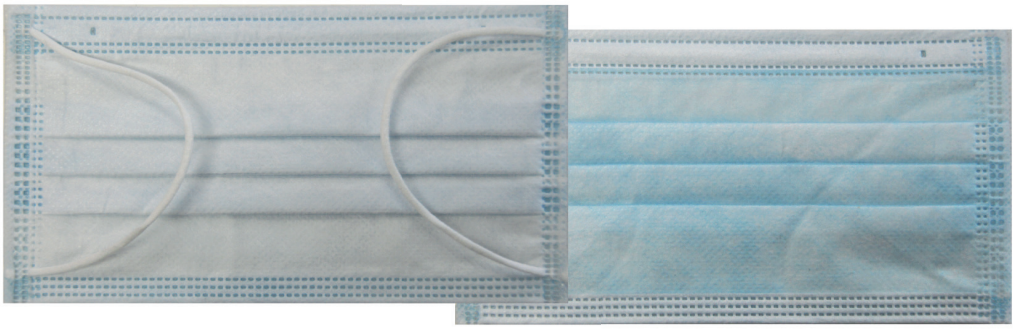
For any further questions feel free to send an e-mail to info@rfx-care.com

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

Face mask

Technical data sheet



ID name: Non-woven 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

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:
5 Years

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

EC-Representative:
RRFX+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

For further information please send your request to info@rfx-care.com

Intended use:

Instruction for use:

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

Axel Heides Gade 1 T +45 44 88 95 95 med-udstyr@dkma.dk
DK-2300 København S F +45 44 88 95 99 www.medicinskudstyr.dk

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	

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

DAkkS
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:
Walmart (China) Investment Co., Ltd.
2-5/F, Tower 2 and 1-12/F, Tower 3
SZITIC Square, 69 Nonglin Rd.
Shenzhen, Guangdong, 518000
CHINA

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

Test Article:	Product Name: GV face mask
Purchase Order:	18C005S
Study Number:	1094375-S01
Study Received Date:	06 Sep 2018
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 15
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 - 2.7 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 F2101-14, EN 14683:2014, Annex B, and AS4381:2015.

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 was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C and AS4381:2015.

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 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~174 mm x ~158 mm
Positive Control Average:	2.6 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.1 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Study Director — Janelle R. Bentz, M.S. — FOR

24 SEP 2018
Study Completion Date

1094375-S01

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	>99.9	3.3	32.2
2	>99.9	3.5	33.9
3	99.9	3.7	36.1
4	99.8	3.1	30.1
5	99.8	3.2	31.6

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

PREVENTIA®

2020 March 11

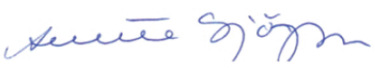
Regulatory statement for face masks CE marked for EU by RFX+Care

In EU we have a risk-based classification of medical devices. The MDD 93/42EEC with the amendment 2007/47/EC clarifies the rules and assessment routes.
For a class I medical device there is no assessment from a Notified Body (NB), but a registration with the Competent Authority (CA). The CE mark must not be accompanied by a NB number. There will be no EC certificate either as there is no assessment by a NB. From the CA a Free Sales Certificate can be issued explaining the free movement of class I CE marked medical devices.

The RFX+Care face mask is a class I medical device per rule 1 in the MDD. It shall be CE marked without any NB number as it is non-sterile.

RFX+Care has a ISO 13485:2016 Quality Management System (QMS) certificate and the QMS has been audited by a NB, TÜV SÜD, a NB that also is designated for the EU Medical Device Regulation 2017/745.

There is no possibility from a regulatory point to receive a EC certificate for a class I medical device unless it is sterile, have a measuring function or is a reusable surgical instrument. The face mask is non-sterile, has no measuring function and is not a reusable surgical instrument.



Anette Sjögren
MSc, Consultant
PREVENTIA AB

Bios

Anette has over 30 years of experience from medical device and pharma industry as QA, RA, QP and the tasks within those fields such as clinical affairs,microbiology, toxicology and biocompatibility.

Anette is a member of the Swedish (TK355) and the international Technical (TC210) committees since 2010.Focus is within the working groups for quality and risk management. Since 16 years Anette is a consultant within PREVENTIA.

As a consultant Anette supports in all kind of activities within the scope of her knowledge and experience such as; giving training courses (open or company internal) and presentation at conferences, participate in projects for market clearance worldwide, perform audits including sterilization and support in clinical affairs as well as quality and regulatory affairs.

Anette holds a MSc in Biomedicine.

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