

FPM2 MASK FONNA

STAY PROTECTED!

Project- Respiratory FPM2 and FPM3 Face Masks,
Against the Coronavirus SARS-COV-2, Made in Germany

Mematec  Solutions



LIST OF TOPICS

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Mematec Solutions is a Business

Unit of Mematec Products

- It is active in the area of design and development of inhalation medical devices used in the treatment of COPD
– Capsule DPI and MDPI

Other Business Units of

Mematec Products are:

- Special Sports Equipment
- Mematec Consulting



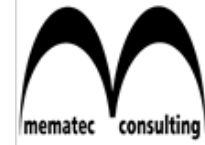
SPECIAL SPORT EQUIPMENT

- Heated sport equipment
- Orthopedic support belts
- Headlamps



MEMATEC SOLUTIONS

- Dry Powder Inhalers
- Design of format parts
- Design of small machines



MEMATEC CONSULTING

- Product Management
- Project Management
- Machine Specification Design

- The Mematec Team covers the total cycle of device development from powder formulation until the end of line packaging.
- Our understanding of powder formulation, powder filling, foil handling or even assembly is based on more than 20 years experience in leading positions of well-known machine manufacturing companies.
- Sound experience of plastic molding is part of the core competence. These skills make our company unique in the world market.
- Mematec is validated and audited according to Pharma Manufacturing Norm ISO 13485.

A ISO 13485:2016 CERTIFICATE

bsi.



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **Mematec Products GmbH**
August-Müller-Straße 24
Freiberg am Neckar
71691
Germany

Holds Certificate Number: **MD 723224**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, development, manufacture, sales and distribution of dry powder inhalers.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-01-29

Effective Date: 2021-01-29

Latest Revision Date: 2021-01-29

Expiry Date: 2024-01-28



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...making excellence a habit™

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Information and Contact:
BSI Group The Netherlands B.V., John H. Kaymeulen 5, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33294284 | A Member of the BSI Group Holdings B.V.

Certificate No: **MD 723224**

Location

Mematec Products GmbH
August-Müller-Straße 24
Freiberg am Neckar
71691
Germany

Registered Activities

Design, development, sales and distribution of dry powder inhalers.

Mematec Products GmbH
Gewerbegebiet Ottmarshelmer Höhe
Carl-Benz-Str. 10
Besigheim
74354
Germany

Manufacture and distribution of dry powder inhalers.

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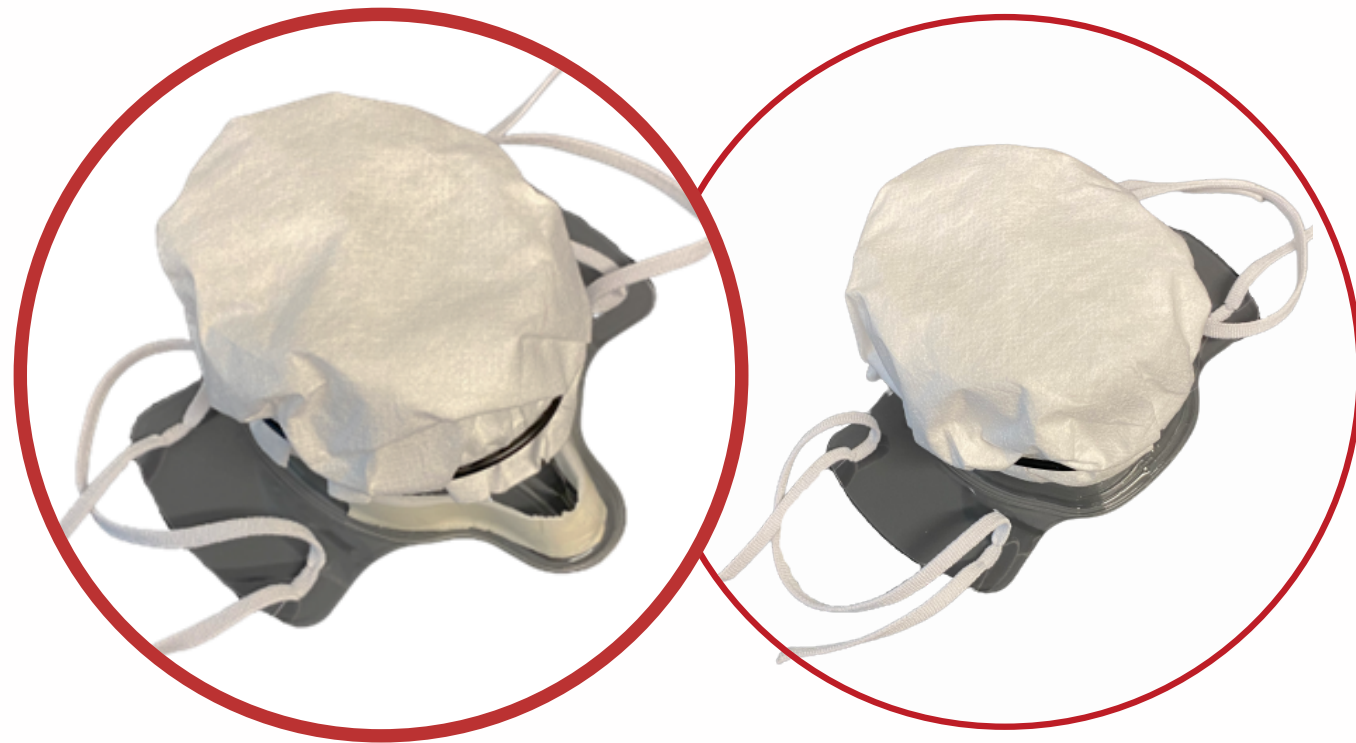
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Mematec Solutions

Since this Technology is not far from Mematec's core competency, they have developed a completely new type of FPM2 and FPM3 Respiratory protection mask called FONNA.

Our mask is unique and different from all other masks on the world market.



MASK

DEFINITIONS

Various Types of Respiratory Protection Masks

01 Mouth-Nose-Protection (OP) Mask

Test Requirement According to EN 14683.

Application: Prevents bacteria and germs from penetrating the surgical wound.



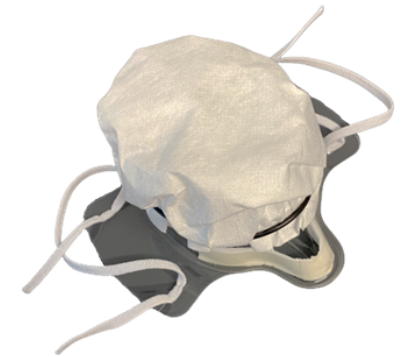
02 Mematec's FPM2/ FPM3 Mask with Interchangeable Filter

Protects the wearer against aerosols / solid particulates and virus / Yes.

Protects the environment / Yes.

Test Requirement According to EN1827 / EN149.

Filter even smallest particles and aerosols.



CHANGEABLE FILTER

03 FFP2 or FFP3 Mask with Exhale Valve

Protects the wearer against aerosols and particulates / Yes.

Protects the environment / No.

Test Requirement According to EN 149.

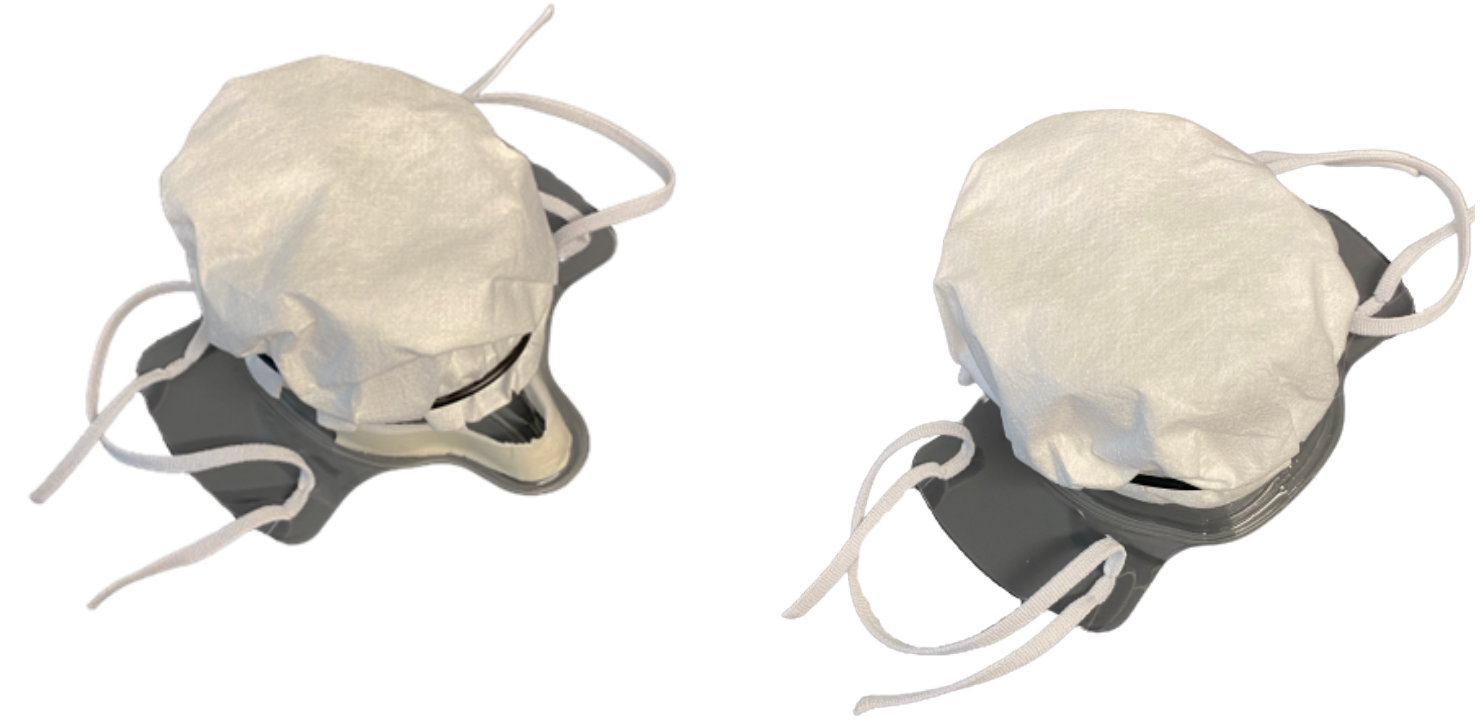


DISPOSABLE FILTER



MEMATEC

MASK FEATURES



Innovative Mask Design

- The self-protection as well as the external protection of people against aerosols and particles is in the foreground of the development.
- Our customers are professional users. Hospital staff, nursing organizations or similar institutions must wear the mask for a long period of time.

- The best wearing and breathing comfort are basic requirements for a good mask. Our mask structure provides maximum protection while at the same time offering unrivaled breathing comfort.
- The mask is patented.

The mematec “Fonna FPM2” mask complies with the requirements of EN1827.

FONNA MASK

Unbeatable Benefits

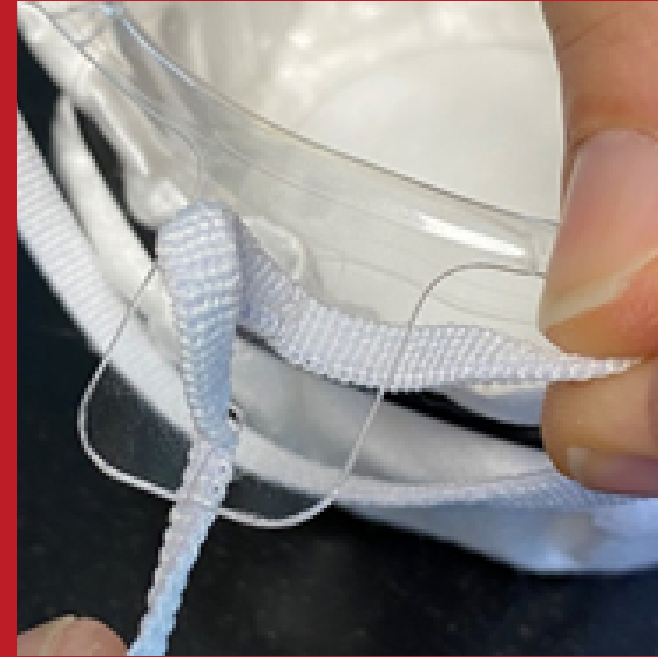


No fogging of eyeglasses.



No direct contact from filter to skin.

Skin-friendly PET contact area.



Adjustable length of rubber bands.



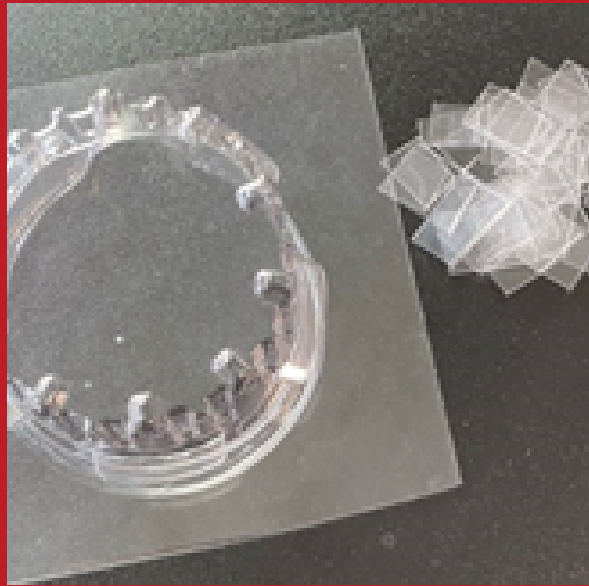
Speak without restrictions.



All parts and materials are made in Baden Württemberg, Germany.

FONNA MASK

Unbeatable Benefits



- ✓ The mask is recyclable.
- ✓ Re-use of the mask body. The recovered granulate can be processed into a new mask again.



- ✓ The filter can be exchanged and the mask can be used several times.



- ✓ FFP2 / FFP3 filter material - for immediate and easy changing.



- ✓ 6-layer filter material for protection of particles and aerosols.



INHALE



EXHALE

Best breathing comfort due to restricting and expanding filter during inhalation and exhalation.

TECHNOLOGY INTRODUCTION

FFP2 MASK

- Minimum 94% aerosol filtration
- Maximum 8% internal leak rate
- Exhalation resistance: 160l/min <3 mbar
- Inhalation resistance: 95l/min bei 2,4mbar / 30l/min 0,7mbar
- Filter permeability: 200Pa = 210l(m²/s)
- Effective filter surface: 33.000mm²
- Tested to the requirements of EN 1827

Recommended Use FFP2: protection against solid and liquid harmful dusts, fumes and aerosols; working environments where harmful and mutagenic substances are present (metal industry and mining)



FFP3 MASK

- Minimum 99% aerosol filtration
- Maximum 2% internal leak rate
- Exhalation resistance: 160l/min <3 mbar
- Inhalation resistance: 95l/min bei 3,0mbar / 30l/min 1,0mbar
- Filter permeability: 200Pa = 240l(m²/s)
- Effective filter surface: 33.000mm²
- Tested to the requirements of EN 1827

Recommended Use FFP3: protection against toxic and harmful dusts, fumes and aerosols; working environments where toxic, carcinogenic and radioactive particles are present (chemical industry)



Click for more Info: <https://youtu.be/dGw3fXkFtqo> (English)

USER MANUAL

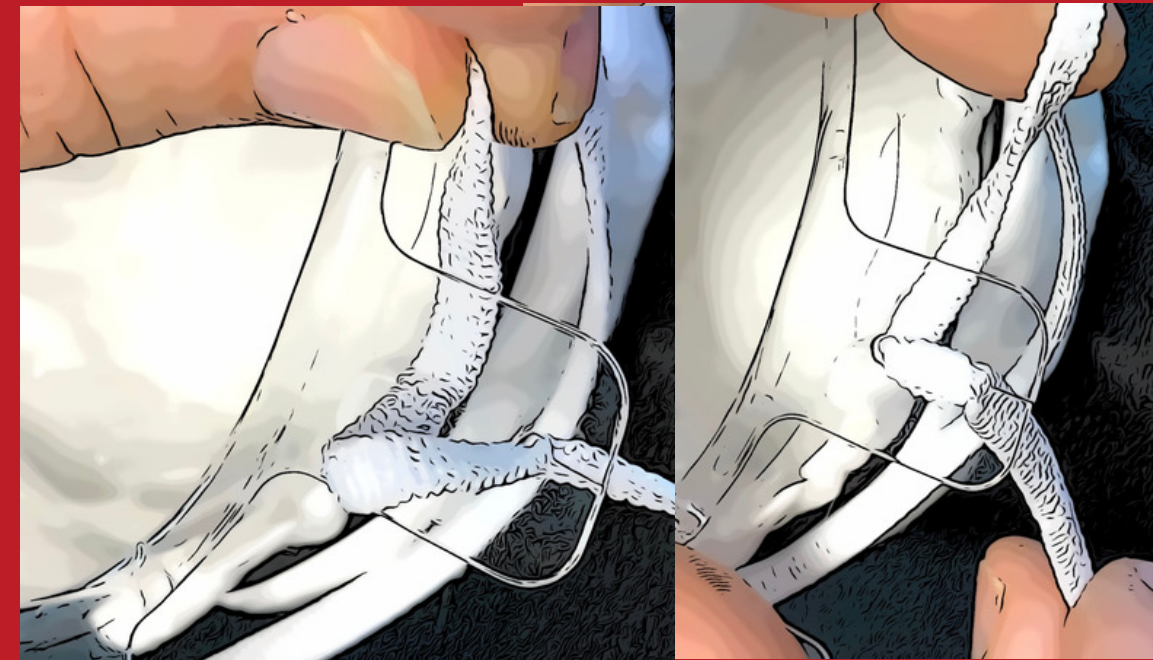
Operating Instructions with Pictograms



Place the rubber bands
sideward and grab them
with your hands.



Put the mask on your
chin and pull the rubber
bands behind the ears.



Adjust the rubber bands
as needed.



Make sure that the mask
fits comfortably and snugly
against the face contour.

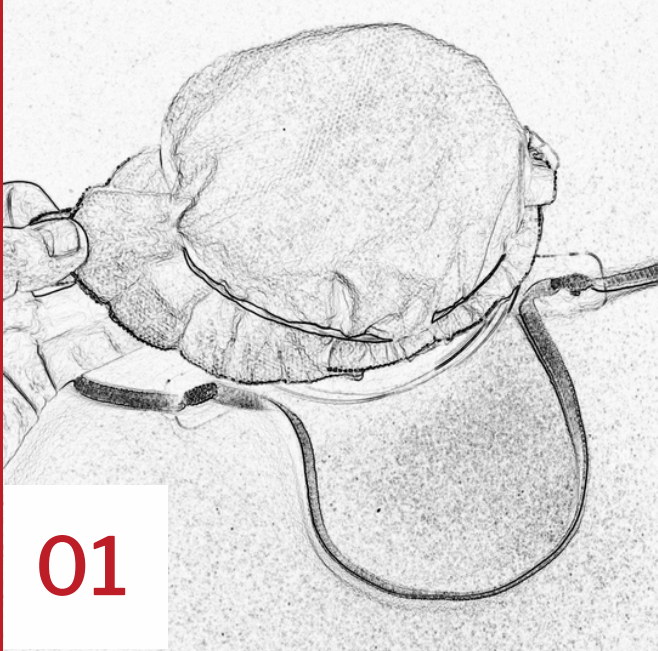
Attention:

Only an optimal fit ensures
that the mask offers the
defined protection!

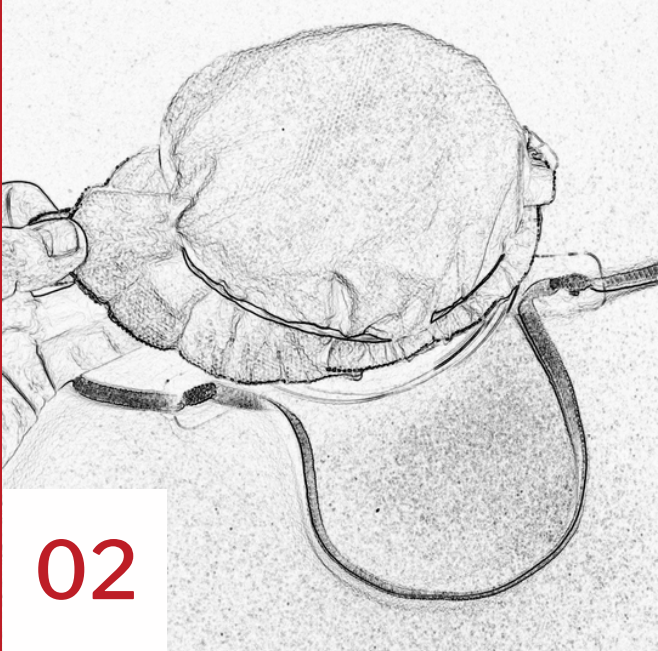
CORRECT USE: In order for an FPM mask to develop its full protective effect, it must be used in accordance with these enclosed instructions for use. Among other things, the correct fit of the mask on the face and the course of the straps must be ensured.

USER MANUAL

Filter Change



To remove the old filter, grab the tab above.



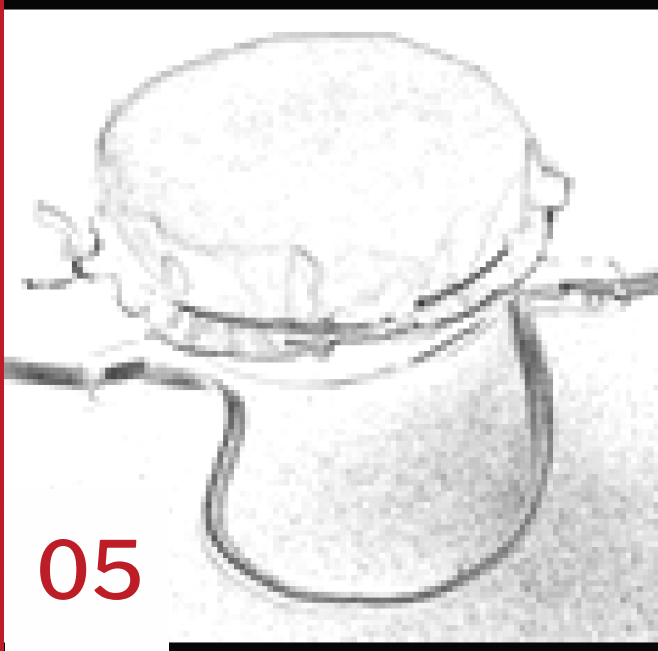
Use the tab to pull the filter off the mask body.



Wash the mask body in soapy water and rinse it with clear water. Let the mask body dry or dry it with a cloth or air dryer. Disinfect the dried mask body.

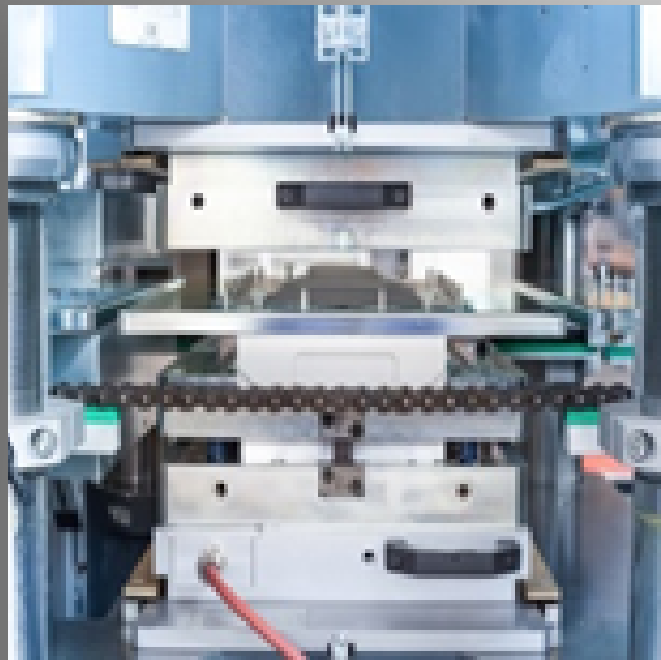


Place a new filter on the mask body and put on the O-Ring. The filter must be pulled evenly over the O-Ring holders.



Control: After changing the filter, the tightness of the filter must be checked. The filter must have a distance of at least 2mm to the O-ring.

THE PRODUCTION PROCESS



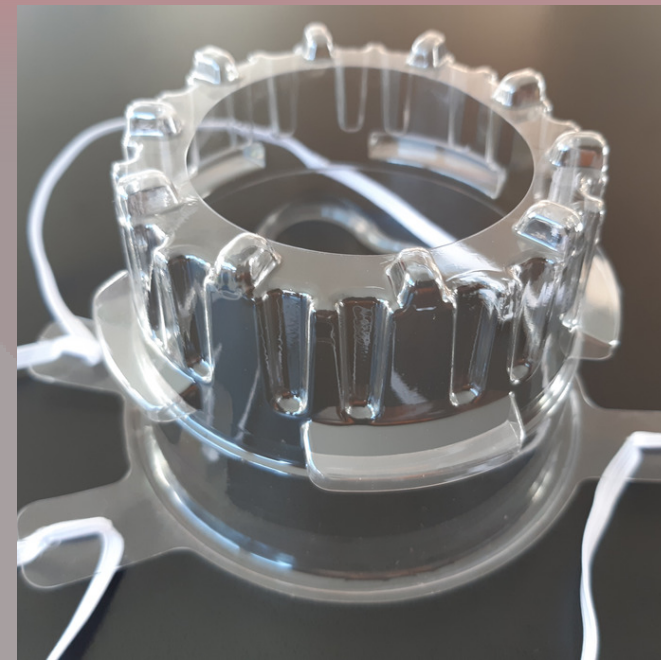
**THERMOFORMING
OF MASK BODY**



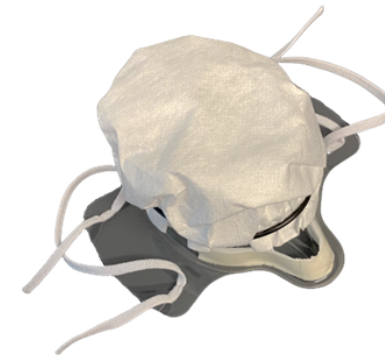
INSTALLING THE FILTER



RUBBER FIXING



**MASK QUALITY
CONTROL**

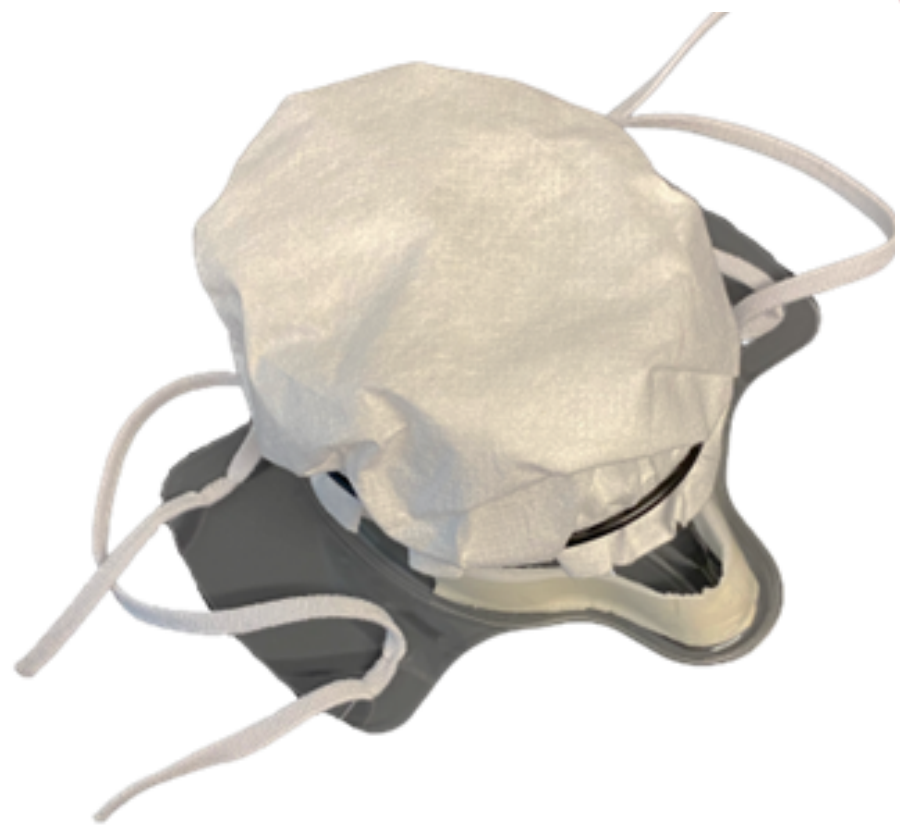


PACKAGING

EU DECLARATION OF CONFORMITY

ACCORDANCE WITH EN 1827 CE

The required certification is currently under process and we expect to receive our EU Declaration of Conformity towards 03/2021



CONTACT US



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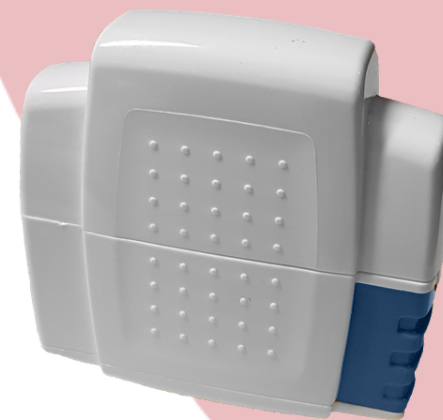


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