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Product information

Surgical face mask
ProfessionalMed TYPe IIR
Elastic ear loops & flexible nose clip for optimal fit

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# 1 Information on how to use this product information sheet

## 1.1 Explanations

We would like to thank you for purchasing the surgical protective mask from Nitto.

The surgical protective mask is intended to be worn on the body to protect others (e.g., patients in a medical setting) from exposure to potentially infectious respiratory secretions (e.g., splashes, droplets, or sprays) from the person wearing the mask. The mask covers the mouth and nose and provides a barrier to minimise direct transmission of infectious germs. The mask prevents droplets from the wearer's breathing air from being released into the environment. Furthermore, the masks have a splash-proof layer to protect the wearer from blood and other body fluids.

**WARNING!** Improper handling and use can cause danger and damage. To avoid personal injury and damage to property, also comply with the safety instructions.
If you have any questions about the contents of this product information sheet or the use of the product, please contact us.
Your Nitto team.

## Scope of application

These instructions for use apply to the following products as well as product versions and product variants:

| Product | Article number |
|---|---|
| ProfessionalMed Type IIR | 3EL00150 |

## Contact details of the manufacturer

Nitto Advanced Film Gronau GmbH
Jöbkesweg 11,
48599 Gronau, Germany
Tel: +49 (0) 2562 919 333
www.nitto.com

# 2  Purpose

## 2.1  Medical purpose

In the following technical documentation, the term "protection" is used when the mask complies with the corresponding requirements for the mask type according to EN 14683.
A type II mask thus corresponds to a bacterial filtration performance of ≥ 98%.
The medical face mask is intended to be worn on the body to protect others (e.g. patients in a medical setting) from exposure to potentially infectious respiratory secretions (e.g. splashes, droplets) from the person wearing the mask. The mask covers the mouth and nose and provides a barrier to minimise direct transmission of infectious germs. The mask prevents droplets from the wearer's breathing air from being released into the environment. The mask serves the prevention of diseases and is therefore a medical device according to article 2 of Regulation 2017/745.

WARNING:
The product is intended for short-term single use.
The mask in use must not be shared with others.

Since no protective effect of the person wearing the mask is intended, the mask is not personal protective equipment (PPE).

## 2.2  Indication(s)

The mask does not serve any specific indication. The indication corresponds to the medical purpose.

## 2.3  Contraindications/exclusions/restrictions

WARNING:
The mask must not be worn for the wearer's own protection.
As the mask is not supplied sterile, it must not be used in sterile rooms with high sterility requirements.

## 2.4  Intended patient target group(s)

The patient group includes all persons who are in the immediate vicinity of the carrier and is not restricted in its characteristics.

## 2.5  Intended users

Primary users are all users who wear the mask for the stated medical purpose. This can include both specialised medical staff and non-specialists. Users do not need any specific previous knowledge to use the product.

## 2.6  Intended use environment(s)

The medical product is not intended or restricted for use in any particular environment. A common application environment is the use in healthcare facilities.

# 3 Important safety instructions

**Important!** Read all safety instructions carefully before using the product. Follow the safety instructions to avoid injuries and life-threatening situations.

Intended for single use only.
Try to touch the mask only as much as necessary during all working steps.
Do not hang the mask loosely around your neck at any time.
Medical masks do not provide full protection against infection, so follow applicable hygiene measures.
Do not use damaged masks.

## 3.1 Putting on the mask

Step 1



Only touch the mask on the ear loops and with washed or disinfected hands. The white inside must face you. Do not touch the mask body.

Step 2



Hold the mask with the nose clip upwards and secure it behind your ears with the ear loops.

Step 3



Press the nose clip comfortably to your nose so that the mask fits as close as possible.

Step 4



Pull the folds apart. Place the bottom of the mask under your chin so that it completely covers your mouth.

## 3.2  Taking off the mask

Wash and/or disinfect your hands. Carefully remove the mask from the face by the ear loops. Do not touch the body of the mask. Then immediately dispose of the mask and wash and/or disinfect your hands once more.

## 3.3  Obligation to report

Report all serious incidents (damage, injury, infection, etc.) related to the product to the manufacturer and the competent authority of the EU Member State where you are established.
In Germany, the competent authority is the BfArM. Current contact information can be found on the BfArM website: https://www.bfarm.de.

### 3.4 Contraindication

The mask may not be suitable for every type of user due to an inadequate fit. Therefore, the mask should not be used by children under 12 years of age.

The mask must not be worn by persons who are unable to wear the mask as prescribed due to mental or physical limitations.
Users should be able to understand the documentation (e.g. labelling).

### 3.5 Requirements for the usage environment

There are no specific requirements regarding the application environment. Neither the lighting conditions, the ambient noise, the social environment nor the furniture affect the usability or intended use of the product in any way.

### 3.6 Avoid risk of infection

Damage to the packaging can lead to infection from a contaminated product.
- ➔ Before using the product, check that the packaging is undamaged.
- ➔ Do not use the product if the packaging is damaged.
- ➔ If infections occur, consult a doctor.

# 4 Product description

## 4.1 Functional principle of the product and process overview

The product consists of an outer layer, a so-called "melt-blown" filter, and an inner layer. Three horizontal folds can be unfolded so that the user can expand the mask to cover the area from nose to chin.
The mask is secured with elastic ear loops that are placed behind the ears, and a metal nose clip (wire) in the upper long section allows the user to fit the mask perfectly around the nose and avoid open crevices. The mask prevents droplets from the wearer's breathing air from being released into the environment.

The surgical face mask consists of a 3-layer composite with universal fit, elastic ear loops and flexible nose clip.
- Dimensions when folded: 175 x 95 mm
- Colour: Blue
- Ultrasonically welded ear loops

Composition:
- Exterior: Liquid-repellent nonwoven, polypropylene, blue
- Filter medium: Melt-blown fleece, polypropylene
- Inside: Skin-friendly nonwoven, polypropylene, white
- Ear loops: Elastane and polypropylene
- Nose clip: Iron and polyethylene

## 4.2 Product conformity

The product complies with the following regulatory requirements
- (EU) 2017/745
- EN 14683:2019 + AC:2019
- ISO 14971:2019
- EN 62366-1:2015 + AC:2020
- EN ISO 10993
- EN 15223-1:2007

## 4.3 Shelf life

The shelf life is indicated on the packaging.

## 4.4 Duration of use

The product is a single-use product.
If the mask body is soaked, a new mask should be used.

# 5   Transport, storage

Store at room temperature in a dry and airy place.
The product should not be exposed to direct sunlight during storage.
No special precautions need to be taken to prevent exposure to moisture/humidity, as the packaging with the tubular bag material is airtight and watertight.

## 5.1   Packaging, scope of delivery

The masks are supplied in flowpacks or boxes of 50 pieces.

To protect the masks from environmental influences, they are packed as follows:
- Wrapper: welded airtight
- Outer carton: printed / labelled

# 6   Disposal

## 6.1   Disposal

The masks fall under the category "standard waste" and shall be disposed of accordingly.
Cleaning, reuse and sterilisation therefore do not apply to this product.

# 7   Technical data

## 7.1   Performance data

Medical mask type IIR
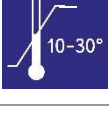
**Type IIR**
Bacterial filter efficiency (BFE): ≥ 98 %
Pressure difference (Pa/cm^2): < 60
Splash resistance pressure (kPA) >= 16.0
Microbiological purity (CFU/g): <= 30

# 8   Symbols used on the product and labelling

| Symbol | Meaning |
|---|---|
| | Manufacturer |
| | Usable until |
| MD | Medicinal product |
| LOT | Production batch |
| REF | Reference / Article number |
| 10-30° | Store product in the specified temperature range |
| | Store the product indoors and protect it from environmental influences |
| | Protect from moisture |
| | Disposable product; do not reuse! |
| | Do not use if packaging is damaged. |
| CE | CE marking; compliance with (EU) 2017/745 |

# 9 Other information

The information provided in this product information sheet is based on our current knowledge at the time of publication. The information provided is intended as a guide to the safe handling, processing, storage, transportation and disposal for the above product and shall not be construed as a warranty or quality specification for which Nitto Advanced Film Gronau GmbH assumes any legal responsibility. As the use of this information and the conditions of use of this product are not under the control of Nitto Advanced Film Gronau GmbH, it is the responsibility of the user to ensure that the product is fit for the particular purpose and to establish the conditions for the safe use of the product. All information listed refers only to the product specifically mentioned above.