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## Instructions for use for medical devices:

to EU 2017/745 and EU 207/2012

Version 1.0 as of 01.05.2021.

### Trade name:

Opharm IIR Medical Mask

### Manufacturer:

Opharm

Pokrzywnica 62, 91-120 Pokrzywnica

Identification / UDI:

590430208SANIDM01PV Opharm IIR Medical Mask - Blue

590430208SANIDM02PX Opharm IIR Medical Mask - Black



### Type:

Medical face masks

Type IIR EN 14683:2019-10

### EU conformity assessment:

Class 1 medical device according to EU 2017/745

### Item types:

Opharm IIR Medical Mask - Blue - pack of 50pcs per box

Opharm IIR Medical Mask - Black pack of 50pcs per box

Opharm IIR Medical Mask - Blue - pack of 10pcs in foil

Opharm IIR Medical Mask - Black - pack of 10pcs in foil

### Objective:

To protect patients and others from pathogens to avoid the risk of spreading infection, especially in pandemic situations.

### Features:

Bacteria capture efficiency (BFE)  $\geq 98\%$

Breathability  $< 60 \text{ Pa/cm}^2$

Microbiological purity  $\leq 30 \text{ KBE/g}$

Splash protection  $\geq 16.0 \text{ kPa}$

Latex, nickel and fibreglass free.

### Indications:

Staying in an environment where an action is required or recommended to reduce the risk of infection to the user or others.

### Contraindications:

There are no general contraindications to the use of medical face masks. Restrictions may be due to the geometry of the mask in relation to the shape of the user's head (close fitting mask and covering of mouth and nose, see "Intended user" above) or medical conditions, in which a small increase in breathing resistance cannot be tolerated. Consult your doctor if you have any medical conditions.

### User:

Adolescents and adults in the general population, including patients and staff in healthcare settings such as in an operating theatre. The requirement in the user guide for the mask to cover the nose and mouth of the user and that the tight fit of the mask is via the ear loops excludes some users, such as infants.

### Usage:

Non-sterile for disposable use

Used masks are considered highly contaminated

No cleaning / disinfection

Observe instructions for use, warning and safety guidelines.

Temperature range  $-5^{\circ}\text{C}$  -  $+40^{\circ}\text{C}$

### Incident reporting

All serious incidents occurring in connection with the product must be immediately reported to the manufacturer and to the competent authority.

### Storage conditions:

Temperature range  $-30^{\circ}\text{C}$  -  $+70^{\circ}\text{C}$

Relative humidity  $< 80\%$

### Storage time:

2 years in original packaging under storage conditions

### Application

1. Before applying the medical face mask, wash your hands with soap and water for at least 20 seconds. Remove the mask from its packaging and with both hands hold it by the ear loops. Check the mask for damage and dirt before use.

2. The upper part of the mask has a built-in flexible wire, which is used to adjust the pressure of the mask against your nose. Place the mask with the white side facing inwards, so that it covers your nose and mouth. Place both ear loops over your ears to ensure a tight fit of the mask.

3. Shape the bridge of your nose with both index fingers from the inside out to the dorsum of the nose.

4. Pull the lower part of the mask over your chin. The mask should fit tightly against the ridge of your nose and cheeks. Avoid touching the mask while in use. The mask should be replaced every two hours or when wet. Disposable products should not be worn more than once and should only be used by one person.

5. To remove the mask, grasp it by both ear loops. Dispose of the mask directly in a closed waste container. Wash/disinfect hands afterwards.

## Safety warnings and instructions

- Follow the operating instructions and all safety instructions for this product.
- Failure to do so may reduce the effectiveness of the medical face mask.
- Wash/disinfect hands thoroughly before putting on the mask and after removing it.
- Avoid touching the mask and face with your hands when using the mask.
- The mask must cover the mouth and nose and must not be worn under the chin.
- After use, dispose of the protective face mask in accordance with local disposal regulations.
- The protective face mask is intended for single use only.
- Do not use an already used or very dirty protective mask, but dispose of it immediately.
- Comply with the recommended or mandatory replacement intervals for the face mask in accordance with occupational safety guidelines or hygiene regulations.



### [DE] Bedeutung der verwendeten Symbole

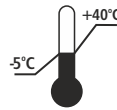
### [EN] Meaning of the symbols used

### [FR] Signification des symboles utilisés

### [PL] Znaczenie użytych symboli



- [DE] Gebrauchsanweisung vor Verwendung lesen  
 [EN] Read manufacturer information before use  
 [FR] Lisez les informations fournies par le fabricant avant utilisation  
 [PL] Przed użyciem należy zapoznać się z informacjami dostarczonymi przez producenta



- [DE] Temperaturbereich der Lagerbedingungen  
 [EN] Temperature of storage conditions  
 [FR] Température en conditions de stockage  
 [PL] Warunki przechowywania - temperatura



- [DE] Maximale Feuchte der Lagerbedingungen  
 [EN] Relative humidity of storage conditions  
 [FR] Humidité relative en conditions de stockage  
 [PL] Warunki przechowywania - wilgotność względna



- [DE] Nicht zur Wiederverwendung  
 [EN] Not to be re-used  
 [FR] Ne pas réutiliser  
 [PL] Jednorazowego użytku



- [DE] Artikel-Nr  
 [EN] Part no  
 [FR] Réf  
 [PL] Nr art



- [DE] Ende der Lagerzeit  
 [EN] End of storage period  
 [FR] Fin de la durée de stockage  
 [PL] Koniec okresu przechowywania



- [DE] Medizinproduct  
 [EN] Medical product  
 [FR] Produit médical  
 [PL] Produkt medyczny



- [DE] Chargen Nummer  
 [EN] Batch number  
 [FR] Numéro de lot  
 [PL] Numer partii



- [DE] Einmalige Produktkennung  
 [EN] Unique Device Identifier  
 [FR] Identifiant unique du produit  
 [PL] Niepowtarzalny identyfikator produktu



- [DE] Nicht steril  
 [EN] Not sterile  
 [FR] Non stérile  
 [PL] Produkt niesterylny



- [DE] Vertriebspartner  
 [EN] Sales partners  
 [FR] Distributeur  
 [PL] Partner handlowy



- [DE] Hersteller  
 [EN] Manufacturer  
 [FR] Fabricant  
 [PL] Producent



- [DE] Vor Hitze schützen  
 [EN] Protect against heat  
 [FR] Protéger de la chaleur  
 [PL] Chronić przed nagraniem