



Instructions for use for a medical face mask

version 4.0 from 26/06/2026

Manufacturer:

Opharm Sp. z o.o.
Ul. Omłotowa 23
94-251 Łódź

Identification / UDI:

590430208SANIDM01PV	Opharm IIR Medical Mask SANI-DM-01 Blue
590430208SANIDMK017Y	Opharm IIR Medical Mask SANI-DM-K01 Blue
590430208SANIDM02PX	Opharm IIR Medical Mask SANI-DM-02 Black
590430208SANIDM03PZ	Opharm IIR Medical Mask SANI-DM-03 Pink
590430208SANIDM04Q3	Opharm IIR Medical Mask SANI-DM-04 Green
590430208SANIDM05Q5	Opharm IIR Medical Mask SANI-DM-05 Navy
590430208SANIDM06Q7	Opharm IIR Medical Mask SANI-DM-06 Maroon
590430208SANIDM07Q9	Opharm IIR Medical Mask SANI-DM-07 Pastel Yellow
590430208SANIDM08QB	Opharm IIR Medical Mask SANI-DM-08 Pastel Purple
590430208SANIDM09QD	Opharm IIR Medical Mask SANI-DM-09 Pastel Salmon
590430208SANIDM10PW	Opharm IIR Medical Mask SANI-DM-10 Pastel Pink
590430208SANIDM11PY	Opharm IIR Medical Mask SANI-DM-11 Pastel Lime
590430208SANIDM12Q2	Opharm IIR Medical Mask SANI-DM-12 Pastel Turquoise

Type:

Medical face masks type IIR EN
14683:2019-10

EU conformity assessment:

Class 1 medical device in accordance with EU 2017/745

Purpose:

Protection of patients and other persons against pathogens in order to avoid the risk of spreading infection, particularly in pandemic situations.

Performance characteristics:

Bacterial filtration efficiency (BFE) $\geq 98\%$ Breathability $< 60 \text{ Pa/cm}^2$

Microbial cleanliness $\leq 30 \text{ CFU/g}$ Splash

resistance $\geq 16.0 \text{ kPa}$ Does not contain latex,
nickel or glass fibre.

Indications:

Presence in an environment where measures to reduce the risk of infection for the user or other persons are required or recommended.

Contraindications:

There are no general contraindications to the use of medical face masks. Limitations may result from the geometry of the mask in relation to the shape of the user's head (close fit of the mask and covering of the mouth and nose, see "Intended user" above) or from health conditions in which a slight increase in breathing resistance cannot be tolerated. In the event of any discomfort, consult a doctor.

User:

Adolescents and adults from the entire population, including patients and staff of healthcare facilities such as, e.g., the operating room. The requirement set out in the instructions for use that the mask cover the user's nose and mouth and that a tight fit of the mask be achieved by means of ear loops excludes certain users, such as, e.g., infants.

Use:

Non-sterile, for single use

Used masks are considered highly contaminated No cleaning / disinfection

Observe the instructions for use, warnings and safety instructions.

Mask operating temperature range -20°C – +40°C

Incident reporting:

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

Storage conditions:

Temperature range -5°C – +40°C

Relative humidity < 60%

Storage time:

2 years in the original packaging, subject to compliance with the storage conditions

Application

1. Before putting on the medical face mask, wash your hands with soap and water for at least 20 seconds. Take the mask out of the packaging and hold it by the ear loops with both hands. Before use, check that the mask is not damaged or soiled.
2. The upper part of the mask features a built-in, flexible wire used to fit the mask snugly against the nose. Put on the mask with the white side facing inwards so that it covers the nose and mouth. Place both ear loops over your ears to ensure a tight fit of the mask.
3. Shape the bridge over the nose with both index fingers, moving from the centre outwards to the bridge of the nose.
4. Pull the lower part of the mask over your chin. The mask should fit closely against the bridge of the nose and the cheeks. Avoid touching the mask during use. The mask should be replaced every two hours or when it becomes wet. Single-use products should not be worn more than once and may be used by only one person.
5. To remove the mask, grasp it by both ear loops. Dispose of the mask directly into a closed waste container. Then wash / disinfect your hands.

Warnings and safety instructions

- Follow the instructions for use and all safety instructions for this product.
- Failure to comply with this requirement may reduce the effectiveness of the medical face mask.
- Before putting on the mask and after taking it off, thoroughly wash / disinfect your hands.
- During use, avoid touching the mask and your face with your hands.
- 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 mask is intended for single use only.
- Do not use an already used or heavily soiled protective mask; instead, hand it over for immediate disposal.
- Observe the recommended or applicable 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] Maximale Feuchte der Lagerbedingungen
 [EN] Relative humidity of storage conditions
 [FR] Humidité relative en conditions de stockage
 [PL] Warunki przechowywania - wilgotność względna



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



[DE] Batch numer
 [EN] Chargen Nummer
 [FR] Numéro de lot

[PL] Numer partii



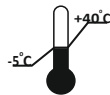
[DE] Nicht steril
 [EN] Not sterile
 [FR] Non stérile
 [PL] Produkt niesterylony



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



[DE] CE-Zeichen
 [EN] CE mark
 [FR] Marquage CE
 [PL] Znak CE



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



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

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



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



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

