

PRODUCT INFORMATION

cleo® med quality (121380)

Medical face masks - type IIR

Premium quality "Made in Germany"



Application range and properties

- + **Maximum protection and comfort:** Quality approved medical face mask type IIR (alternative names: OP masks, mouth-nose protection, MNS masks, surgical masks, protective masks) manufactured in Germany; medical device of class I; partial body protection for the mouth and nose area; 3-layer design; with practical elastic band at the sides; adjustable noseclip; very good sealing fit, soft material for pleasant wearing comfort; low breathability for medical face mask type IIR; suitable for allergic people (latex- and glass fibre-free); non-sterile design.
- + **Application range:** Medical face mask for protection against infectious agents (e.g. bacteria or viruses). The transmission of infectious agents during surgical procedures in operating theatres and other medical facilities can occur in several ways. Sources of infection include the noses and mouths of members of the surgical team. The main intended use of medical face masks is to protect the patient against infectious agents and, in addition, in certain situations, to protect the wearer against splashes of potentially contaminated fluids. Medical face masks may also be used to be worn by patients and others to reduce the risk of spreading infection, particularly in epidemic or pandemic situations.
- + **Typical application areas:** Hospitals, pharmacies, medical practices, nursing homes, police, civil protection, etc.
- + **Standards:** Medical face mask tested in accordance with EN 14683:2019 + AC:2019, the standard-compliant test confirms that the material has a good protective or barrier function against microorganisms (e.g. bacteria & viruses).
- + **Protective properties:** No guarantee for all forms of infectious agents! A medical face mask is primarily designed to prevent the spread of droplets from the nasopharynx of the wearer. At the same time, it should protect the wearer from splashes of the patient's body fluid. The mask protects the user only when used correctly. Protection is limited to the scope of the validity of the test requirements and the achieved test results.
- + **Wearing advice:**
 - PUT ON*
 - 1. Wash or disinfect your hands.
 - 2. Hold mask with nose clip up, coloured side outwards.
 - 3. Pull loops over ears, mask over nose, mouth, chin.
 - 4. Adjust nose clip and side of mask to face contour.
 - TAKE OFF*
 - 1. Wash or disinfect your hands.
 - 2. Take just the ear loops. IMPORTANT: Do not touch the filter surfaces!
 - 3. Masks are infectious waste.
 - 4. Wash or disinfect your hands.Keep away from flames and heat sources.
- + **Change interval:** Frequently, before each operation, or in case of visible contamination or moisture penetration, if possible every 2 hours; in case of visible contamination immediately! Single use! Used masks are considered as heavily contaminated. The following must be taken into account when changing masks: Do not touch the mask body/filter material with your fingers/hands. After changing, the hands must be disinfected or the gloves changed. The mask is worn over the nose and mouth and must not hang around the neck of the wearer at any time. Used masks must be disposed of immediately due to the potential for cross-contamination.
- + **Before use:** Check for damage! Do not use damaged face masks!
- + **Disposal:** Waste requiring monitoring (waste code: 18 01 04 according to 2000/532/EC), waste requiring special monitoring¹⁾ (waste code: AS 18 01 03*¹ according to 2000/532/EC); collect and dispose of separately!

1): Waste types marked with (*) in the waste list are hazardous. Waste whose collection and disposal is subject to special requirements in order to prevent infection.

Type

Order No. / REF.	121380
Size	Uni
Packaging unit	50 pieces
Version	Non-sterile

Material properties

Material	Polypropylene + Filter-Polypropylen (melt-blown filter) + Polypropylene
Colour	Blue outside, white inside
Weight of material	25 + 25 + 20 g/m ²
Size (folded)	17.5 x 9.5 cm
Size (open)	17.5 x 17,5 cm
Filter surface	306 cm ²
Total weight packaging	160 g

Biological & physical requirements

Medical face masks - Requirements and test methods according to EN 14683:2019 + AC:2019:

Type of test	Performance requirements (Type IIR)	Result
Bacterial filter performance (BFE), [%] to EN 14683:2019 Annex B	≥ 98	99.82
Breathability [Pa/cm ²] according to EN 14683:2019 Annex C	< 60	51
Spray resistance to penetration of synthetic blood according to ASTM F1862 / ISO 22609:2004 with required test pressure [kPa]	16.0	No penetration
Microbiological purity [CFU/g] according to EN 14683:2019 Appendix D	≤ 30	≤ 13
Additional test	Performance requirements (Growth limit)	Result
Biological evaluation of medical devices according to ISO 10993-5:2009 (cytotoxicity [%])	≤30	25

Care instructions

- + Do not wash
- + Do not iron
- + Do not put in the dryer
- + Not suitable for dry cleaning

CE-marking

CE-marking in accordance to 93/42/EEC Directive for medical devices of class I, tested according to EN 14683:2019 + AC:2019. The EU declaration of conformity can be viewed at www.berner-safety.de.

Quality management system

Our **quality management system** is **tested and certified** by TÜV Management Service GmbH in accordance with DIN EN ISO 9001:2015. The quality of our products is ensured by regular **audits & visits to production sites**.

Storage and transport requirements

- + Dark (protect from direct UV and sunlight)
 - + Cool (+5 until +25°C)
 - + Dry (relative humidity 30% - 60%)
 - + No contact with pointed and/or sharp objects
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Shelf life

2 years from date of manufacture

Manufacturer

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