



Medizinische Gesichtsmaske Transparent
Masque facial médical transparent
Mascherina facciale medica trasparente
Transparent medical face mask
Mascarilla médica transparente

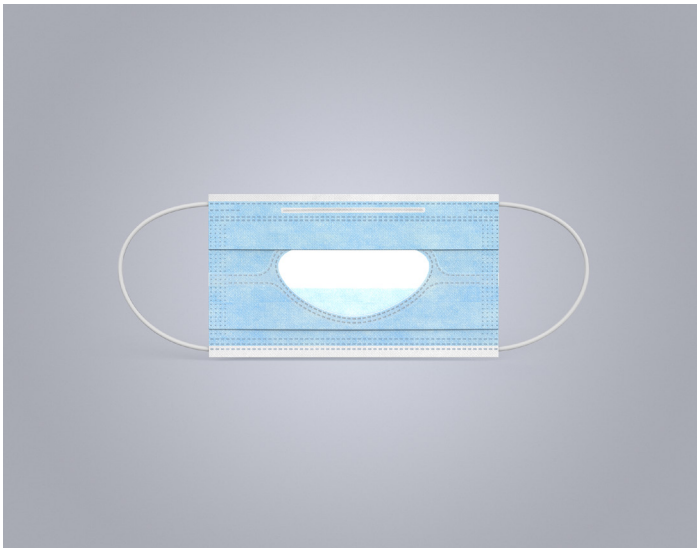
TYP II
MaXsmile 105079



 **Swiss Made**

Medical face masks (Class I medical device) are primarily intended for protection of others and protect against exposure to potentially infectious droplets originating from the person wearing the face mask. Although these masks also protect the wearer of the mask to a limited extent when fitting tightly, it is not their primary purpose.

Technical data sheet



Main characteristics

- Type II medical face masks have a bacterial filter performance of $\geq 98\%$
- Elastic ear straps make it easy to put on and remove the mask
- Flat design enabling space-saving storage
- Nose clip for an optimal fit
- A clear window panel over the mouth allows lip-reading

Review and conformity

Medical devices are subject to the Medical Device Directive MDD RL/93/42/EEC and the Medical Devices Ordinance MDR (EU) 2017 / 745 and are subject to the corresponding conformity assessment procedure. This results in the declaration of conformity and the CE marking on the product and on the packaging, respectively.

Medical face masks comply with the EN 14683:2019+AC:2019 standard "Medical Face Masks – Requirements and Test Methods". The performance requirements are certified by an accredited test laboratory (results are documented in a test and inspection report).

Materials

The following materials are used for the manufacture of this mask:

- Three-layer fleece – outer fleece, filter fleece / meltblown, inner fleece
- Elastic ear strap – polyamide / elastane
- Nose clip – metal / polypropylene
- Mask weight – approx. 3 grams
- Window – CPP (Cast Polypropylene) foil

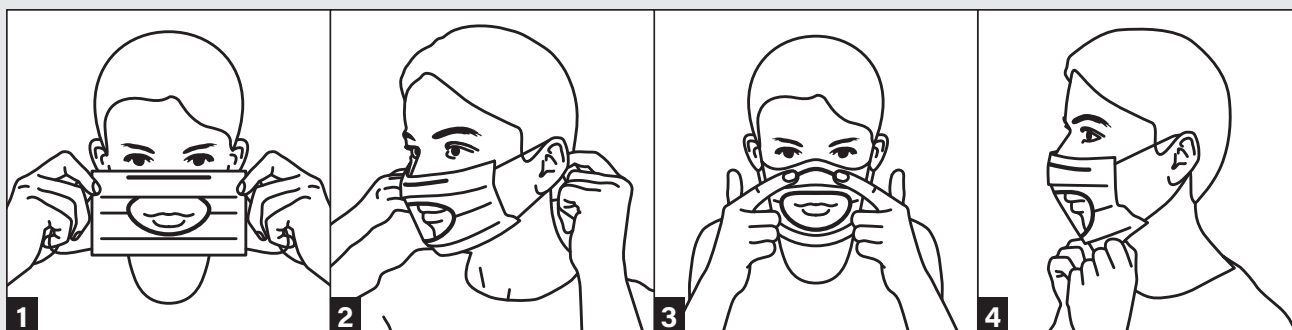
Instructions for use

- The mask is intended for single use and must not be reused.
- Do not touch the mask while wearing it.
- Do not allow the mask to hang around your neck.
- The mask must not be used:
 - if damaged
 - if wetted by breathing air
 - after the end of its use



Putting on and fitting

Wash or disinfect hands thoroughly before putting on the mask



1 Hold the mask by the outer edges only and check for defects

2 Hold the mask by the loops and place a loop around each ear (the coloured side of the mask faces outside)

3 Press along the nose clip

4 Pull the mask over the chin and check the fit. Check if the mask fits tightly

Removing and discarding the mask

Remove the mask carefully without touching the outer or inner side:

1. Hold the ear loops with both hands and pull them over your ears. In doing so, hold the mask by the ear loop only and remove it.
2. Dispose of mask in a closed container
3. Wash or disinfect hands thoroughly afterwards

Packaging units

- Primary packaging: folding box (FB) / 1x shrink bag with 25 masks each = 25 masks
- Secondary packaging: corrugated board box containing 20 folding boxes = 500 masks per corrugated board box (Internal dimensions: 541x381x191 mm, external dimensions: 547x387x203 mm)
- Transport unit: 28 corrugated board boxes per pallet = 14,000 masks (4 boxes per layer, 7 layers per pallet, total height of the pallet 1.566 m)

Storage and Transport

The product should be stored and transported in the original packaging. For further storage conditions and shelf life, see the instructions for use on the back of the folding box.



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