

TECHNICAL DATA SHEET

PRODUCT

MEDICAL FACE MASK

CLASSIFICATION

I CLASS MEDICAL DEVICE

CATEGORY

TYPE II

PRODUCT DESCRIPTION

Prefabricated design rectangular three-layer face mask with a shapeable nose-piece and two earloops present, one on each side, to hold mask in place.



The product covers the nose, mouth and chin of the user to prevent the release of air droplets from the airways of an infected person into the environment to limit the further spread of the infection and to protect the carrier from other environmental hazards.

MATERIAL

| | | |
|------------|---------------------------------|-----------------------------------|
| 1st ply | Outer Material | 25 g/m2 Non-Woven |
| 2nd ply | Filter Layer | 25 g/m2 Melt-Blown filter |
| 3rd ply | Inner Material | 25 g/m2 Fluid resistant Non-Woven |
| Nose-piece | Metal wire covered with plastic | |
| Earloops | Polyester and Spandex | |

Latex free

QUALITY

Norm EN 14683, Type I and Type II limit

| EN 14683 - EFFICACY TESTS | STANDARD / METHOD |
|---|-----------------------------|
| Bacterial filtration efficiency (BFE) | EN 14683:2019 Annex B 5.2.2 |
| Breathability | EN 14683:2019 Annex C 5.2.3 |
| Bioburden method validation | ISO 11737-1:2018 Annex B.2 |
| Bioburden (microbiological contamination) | EN 14683:2019 Annex D 5.2.5 |

FIXTURE

3-layer mask body, with nose-piece on the upper edge of the mask and with ultrasonically welded ear loops inside the mask body.

SIZE

| | | |
|------------|-------------|---------|
| Mask Body | 175 x 95 mm | ± 5 mm |
| Nose-piece | 105 | ± 5 mm |
| Earloops | 165 mm | ± 10 mm |

PACKAGING

50 pcs per box
Size: 18.5 x 10 x 9cm
Weight: 180 g



10 pcs per box
Size: 18.5 x 10.5 x 2.5cm
Weight: 46 g



SHELF LIFE

3 years after production date

STORAGE CONDITION

Store under cool, clean, and dry conditions. Avoid excessive heat (over 40°C or 104°F)

QUALITY ASSURANCE AND CONFORMITY

Directive 93/42/EEC
 Regulation (EU) 2017/745
 (Partly. The entry into force of the Regulation postponed to 26 May 2021 - REGULATION (EU) 2020/561)
 EN 14683:2019

COUNTRY OF ORIGIN

LATVIA