

TECHNICAL DATA SHEET

Date: 08/12/2020

PRODUCT

MEDICAL FACE MASK

CLASSIFICATION

I CLASS MEDICAL DEVICE

CATEGORY

TYPE IIR

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 mask wearer. Its purpose is to reduce 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 IIR 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
Splash Resistance	ISO 22609:2004

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

PRIMARY PACKAGING	SECONDARY PACKAGING
50 pcs per box	40x50 pcs per box
Size: 18.5 x 10 x 9cm	Size: 52 x 39 x 39.5cm
Weight: 180 g	Weight: 7750 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
 ISO 22609:2004

COUNTRY OF ORIGIN

LATVIA