



# Product Technical Sheet

Ref. IC-12-K

Type IIR Surgical Mask with Elastic Bands



**ICEMEDICS**<sup>®</sup>

## Technical Information:

### Manufacturer Model: LHKL-B-1

Type IIR surgical mask made of three layers of non-woven fabric and filter material. Includes a moldable nose strip made of Steel+PP and two soft elastic ear loops for comfort.

1st LAYER	2nd LAYER	3rd LAYER
Non-Woven Fabric 25g	Melt-blown 25g	Non-Woven Fabric 20g

- Nose Clip Length: 11 cm
- Elastic Band Length: 17.5 cm
- Mask Dimensions: 17.5 x 9.5 cm
- Color: Blue
- Latex-Free: Yes
- Graphene-Free: Yes
- Fiberglass-Free: Yes
- Non-Irritating: Yes

## Regulations and Usage:

- Compliant with **EU Regulation 2017/745** on **medical devices - Class I**.
- Manufactured under the standards of **ISO 13485:2003+AC2007**.
- Meets the requirements of **EN 14683:2019+AC:2019**.
- Test Number: GOLMOXKC355595L1
- Accredited Laboratory: CNAS No. L0412

Bacterial Filtration Efficiency	Breathability/Differential Pressure	Microbial Cleanliness/Bioburden	Splash Resistance Pressure
$\geq 98\%$	$< 60\%$	$\leq 30$ UF/g	$\geq 16$

### Instructions for Use:

- Check the condition of the mask and expiry date before use.
- Do not use the mask for more than 4 hours.
- Wash hands before handling the mask and only touch the elastic bands.
- Place the mask over the nose and mouth, securing the elastic bands behind the ears.
- Adjust the nose strip and chin area for a proper fit.
- Avoid touching or manipulating the mask during use.

## Logistics Information:

Labeling in accordance with Standard 14683:2019+AC:2019 and Class I Medical Device.

Presentation:

- Dispenser Pack: 10 units
- Master Carton: 2,500 units (250 dispenser packs)
- Euro Pallet: 30 boxes

EAN Code: 9 6974100420492 - Made in China

Basic UDI-DI: 6974100423599AVC

Store in a dry, clean place at temperatures between 5°C and 35°C. Avoid direct sunlight.