

# Surgical Facemask - Type 2R



Helapet are pleased to offer a Type 2R Surgical Facemask, providing suitable nose and mouth barrier protection for general medical and surgical practice.

Constructed using lint-free, three-layered (3 ply) material, the Surgical Facemask is designed to be comfortable and breathable, whilst providing excellent barrier protection against microorganisms such as viruses and bacteria.

The facemask is also designed to be splash resistant, granting limited protection from body fluid splashes emanating from the patient, in-addition to preventing the spread of moisture droplets from the wearer. The nose wire and elasticated ear loops provide a good and tight fit.

Low particle shedding ensures the facemask is ideal to use in controlled environments including surgical procedures.

#### Features and Benefits

- ✓ CE marked Class I medical device
- Lightweight material for enhanced breathability and comfort
- Splash resistant preventing moisture and droplet contamination
- ✓ High BFP\* performance >99%
- ✓ Secure ergonomic design for close facial fit
- ✓ Latex-free preventing irritation and allergic reactions
- Compliant to EN 149:2001 and EN 14683:2019+A1:2019

\*BFP - Bacterial filter performance

## **Ordering Information**

#### AN29101

Type 2R Surgical Facemask std • non sterile • 50 pcs/pck

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### **Technical Data**

This mask is a medical/surgical type II and type IIR, (R is the splash resistance in accordance with ISO 22609:2004) medical device class I.

	Outer Facing Layer	100 % polypropylene
Material	Inner Facing Layer	100 % polypropylene
	Filter Layer	Meltex 435 (25g/m²)
	Fastening	50 % Polyurethane + 50 % Polyester
	Nose-band	Steel wire with PE wire tie
Colour	Pale blue	
Mask Size	17.5 x 9.5 cm	
Construction	3 ply layered	
Weight	65 g/m <sup>2</sup>	
Properties	Latex free; splash resistant (ISO 22609:2004)	
Bacterial filter performance (BFP), (%) according to EN 14683:2019 Annex B	99.72	
Pressure difference (Pa/cm²) according to EN 14683:2019 Annex C	31-49	
Splash resistance pressure (kPa) according to ISO 22609:2004	Pass	
Microbiological purity (CFU/g) according to EN 14683:2019 - § 5.2.5	≤ 5	
Biological & physical requirements	Medical facemasks - Requirements and test methods according to EN 14683:2019+A1:2019 Bacterial filter performance (BFP), (%) according to EN 14683:2019 Annex	
Fitting/ Type	Ear loops	
Storage and transport requirements	Dark (protect from direct UV and sunlight) Cool (+5 to +40°C); Dry; No contact with pointed and/or sharp objects	
Compliance	CE marking according to 93/42/EEC Directive for medical devices of risk class I, tested according to EN 149:2001 & EN 14683:2019+A1:2019.	
Packaging	50 x facemasks per pack	
Shelf Life	5 years from date of manufacture	

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