### **US INTERNATIONAL** Trade+Marketing GmbH

### TECHNICAL INFORMATION SURGICAL MASK 61604

- High efficiency Antibacterial Multi-layered Antistatic Splashproof TÜV certified
- EN14683 Medical Class II R

# **EARBAND TYPE SURGICAL MASK**













## CE STERILE EO EC REP

### **SURGICAL MASK 61604**

High Performance Polypropylen Surgical Mask, Earband Type, 17cm x 9cm

- Multi-layered, three layers
- Antibacterial
- Antistatic
- High efficiency

- Comfortable
- Splash proof
- No glue
- Safe

#### Made from 5 parts:

- Surface layer made from non-woven spunbond
- Filter layer made from non-woven meltblown material
- Bottom layer made from non-woven spunbond
- Nose clip made from moldable materials achieving 3D shaping feature
- Earloops made from Spandex plastic material

Sealed and sterilized by means of EtO Ethylenoxid sterilization process.

Storage up to 3 years at -5 to +35 C° at a maximum of 80% humidity in non-corrosive ambience under good ventilation.

Authorized representative in the European Community

**EC certified by TÜV Süd** under quality assurance system as per Directive 93/42/EEC on Medical Devices in accordance with MDD Annex V. (Devices in class I in sterile conditions, sterilized systems or procedure packs) valid until 03.02.2021

**DAkkS Deutsche Akkreditierungsstelle , TÜV Süd certified as per EN ISO 13485:2016 Medical Devices** – Quality management systems – Requirements for regulatory purposes DIN EN ISO 13485:2016 valid until 19.01.2021

**EN 14683: 2019 Medical Class II R** tested by ILAC-MRA and IAS accredited test laboratory

### **SURGICAL MASK 61604**

Productinformation			
Product	Surgical Mask		
Model	61604		
Туре	with earloops		
Size	17 x 9 cm (tolerance +/- 1%)		
Lenght Earloop	both sides 15 cm (tolerance +/- 2%)		
Weight	$\geq$ 20g / m <sup>2</sup>		
Construction	three layers		
Colour	blue		
Quality Features	<ul> <li>Multi-layered</li> <li>Antibacterial</li> <li>Antistatic</li> <li>High efficiency</li> <li>Comfortable</li> <li>Splash proof</li> <li>No glue</li> </ul>		
Material	Polypropylen		
	Surface layer	non-woven spunbond	
	Filter layer	non-woven meltblown materia	
	Bottom layer	non-woven spunbond	
	Nose clip	moldable materials	
	Earloops	flexible Spandex plastic material	
Bacterial filtering efficiency	BFE ≥99%		
Particular matter filtering capacity	high PM, ≥ 90%		
Fluid resistance	up to 2ml		
Lateral spray test performance	16.0kPa (120 mm Hg)		
Storage	up to 3 years at -5 to +35 C° at max 80% humidity in non-corrosive ambience under good ventilation		

Packing		
Quantity inner packing (Plastic bag)	25 pcs	
Quantity inner packing (Carton box containing 2 bags)	50 pcs	
Quantity outer carton	2000pcs weight 12,5kg/ carton	
Quantity CCG1 (LxWxH incl. 15cm pallet)	24000pcs (12 outer cartons) 120x100x99cm	
Quantity CCG2 (LxWxH incl. 15cm pallet)	36000pcs (18 outer cartons) 120x100x141cm	
Outer dimensions outer carton in cm	57,0 x 42,0 x 42,0	
Volume outer carton in cbm	0.100548	
Grossweight outer carton in kg	9,5	
Customs tariff number	6307909810	

# **US INTERNATIONAL**

Trade+Marketing GmbH

Mattentwiete 5 20457 Hamburg Germany

**4** +49 40 280 967 55

**♣** +49 40 280 967 56