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Office: BEROMED GMBH HOSPITAL PRODUCTS · Kronenstrasse 19 · 10117 Berlin · Germany

## Summary essential technical data - *BEROMASK* - Sterile oxygen masks for single use

<b><u>Manufacturer:</u></b>	Beromed GmbH Hospital Products Kronenstrasse 19 10117 Berlin GERMANY
<b><u>Product:</u></b>	Oxygen Mask
<b><u>Brand:</u></b>	<i>BEROMASK</i>
<b><u>UMDNS code:</u></b>	12-448
<b><u>Risk Class:</u></b>	IIa according to Annex IX, rule 2 of Council Directive 93/42/EEC, amended by Council Directive 2007/47/EC
<b><u>Conformity assessment procedure:</u></b>	according to Annex II.3 of Council Directive 93/42/EEC, amended by Council Directive 2007/47/EC
<b><u>Notified Body:</u></b>	TUEV Süd Product Service GmbH Ridlerstraße 65 80339 Munich, Germany Identification no 0123

### **Brief description of the product**

*BEROMASK* oxygen masks are medical devices used for the supply of oxygen or other gases to a patient.

They fit snugly over the nose and mouth and are to be connected to an oxygen storage tank by a tube.

*BEROMASK* oxygen masks are available with or without tube - for details, please refer to section "Variants".

*BEROMASK* oxygen masks are sterile and pyrogen-free.

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Registered Office:	Berlin
Managing Director:	Jörg Bartz
Commercial Registry:	Berlin-Charlottenburg HRB 65718
VAT-No.	DE 812 404 118

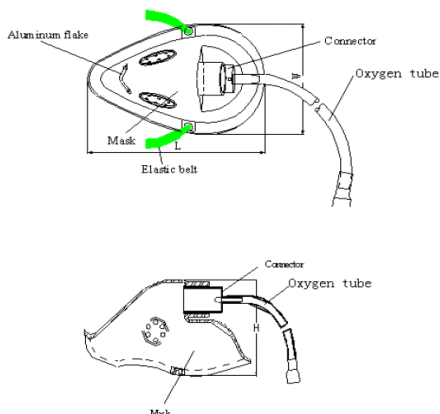


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**Drawing and Material specifications:**



Oxygen Mask

Component	Material
1 Mask	PVC (Polyvinyl chloride polymer), plastizicer DOP (DEHP)
2 Mask connector	PP (Polypropylene)
3 Oxygen Tube	PVC (Polyvinyl chloride polymer), plastizicer DOP (DEHP)
4 Oxygen tube connector	PVC (Polyvinyl chloride polymer), plastizicer DOP (DEHP)
5 Aluminum flake	Aluminum
6 Elastic Belt	Terylene / Ammine

**Features:** sterile, non-pyrogenic  
 comfortable, light in weight  
 transparent plastics leaves the face visible  
 BEROMASK oxygen masks are available with or without tube

**Sterilization:** by Ethylene Oxide (ETO)

**Latex:** BEROMASK oxygen mask is latex free

**Shelflife:** 5 years from the date of manufacture  
*dates of manufacture and expiry are printed on the individual package*

**Storage:** Do not store at extreme temperature and humidity.

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**Precautions for use:**

The operators should be professionally trained healthcare workers.

Check the integrity of the individual package before use. Do not use if the package is damaged.

To be used immediately when individual package is opened.

For single use only.

Re-use of single-use devices creates a potential risk of patient or user. It may lead to contamination and/or impairment of functional capability. Contamination and/or limited functionality of the device may lead to injury, illness or death of the patient.

Discard after single use to avoid risk of infection.

Use within the validity period

Do not use if the patient is known to develop an allergic reaction to any of the material the product consists of.

*Plasticizer DOP (DEHP):*

Animal experiments have shown DEHP to be potentially toxic to reproduction. Given the current state of scientific knowledge, a risk (in case of long-term use) especially for premature male babies cannot be completely excluded. As a precaution, the application of medical products containing DEHP should be restricted to short-term use for pregnant women, breastfeeding mothers, infants and children.

**Packing data:**

	pieces per	dimensions
individual packing (peelable pouch)	1	82 x 125 mm
Export carton	50	0.36 x 0.28 x 0.26 m

**Variants:**

BEROMASK sterile oxygen mask for single use								
Article no	Specification	Length (mm)	Width (mm)	Height (mm)	Length of elastic belt (mm)	Length of oxygen tube (cm)	Outer Diameter of oxygen tube (mm)	Inner Diameter of oxygen tube (mm)
B264105	Adult standard	105±5mm	85±3mm	60±3mm	500±10mm	213±5cm	5.6±0.2mm	3.0±0.2mm
B264129	Adult elongated	130±5mm	85±3mm	65±3mm	500±10mm	213±5cm	5.6±0.2mm	3.0±0.2mm
B264143	Pediatric standard	75±5mm	70±3mm	45±3mm	500±10mm	213±5cm	5.6±0.2mm	3.0±0.2mm
B264167	Pediatric elongated	95±5mm	70±3mm	50±3mm	500±10mm	213±5cm	5.6±0.2mm	3.0±0.2mm
B264112	Adult standard	105±5mm	85±3mm	60±3mm	500±10mm		without	
B264136	Adult elongated	130±5mm	85±3mm	65±3mm	500±10mm		without	
B264150	Pediatric standard	75±5mm	70±3mm	45±3mm	500±10mm		without	
B264174	Pediatric elongated	95±5mm	70±3mm	50±3mm	500±10mm		without	

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