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

**Summary essential technical data - BEROTUBE -  
Sterile oxygen cannula for single use**

**Manufacturer:** Beromed GmbH Hospital Products  
Kronenstrasse 19  
10117 Berlin  
GERMANY

**Product:** Oxygen Cannula (tube)

**Brand:** BEROTUBE

**UMDNS code:** 12-702

**Risk Class:** IIa according to Annex IX, rule 5 of Council Directive 93/42/EEC,  
as amended by Council Directive 2007/47/EC

**Conformity assessment procedure:** according to Annex II.3 of Council Directive 93/42/EEC,  
as amended by Council Directive 2007/47/EC

**Notified Body:** TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 Munich, Germany  
Identification no 0123

**Summarizing regulatory information:**

<b>Name of the product:</b>	Oxygen Cannula
<b>Subcategory (NBOG):</b>	MD 0101
<b>MDS code:</b>	MDS 7006 1 (EO)
<b>Risk class:</b>	IIa
<b>classification rule Annex IX MDD:</b>	5
<b>UMDNS code:</b>	12-702

**Brief description of the product**

**Intended use:**  
BEROTUBE oxygen cannula (tube) is a medical device used for the administration of oxygen to dyspneic patients through both nostrils.

For this purpose, the nasal cannula is placed into both nostrils, and the connector at the proximal end of the tube is attached to oxygen compressors / sources.

The tubing is placed around the patient's ears and fixed under the chin. The design of oxygen cannula allows the patient to eat, drink and talk while the oxygen is administered.

BEROTUBE oxygen cannula are sterile. They are disposable items intended for short-term use (definition as per Annex IX, MDD 93/42/EEC).

**Indication:**

- mild dyspneic or cardiac disorders resulting in reduced oxygenation of the arterial blood

**Contraindications:**

- Hypersensitivity of the patient to any of the materials used
- usage in patients unable to breathe through the nose

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Registered Office: Berlin  
Managing Director: Jörg Bartz  
Commercial Registry: Berlin-Charlottenburg HRB 65718  
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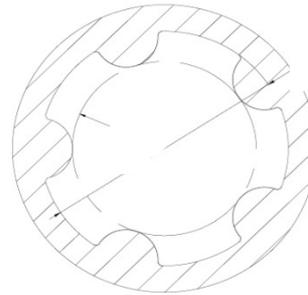
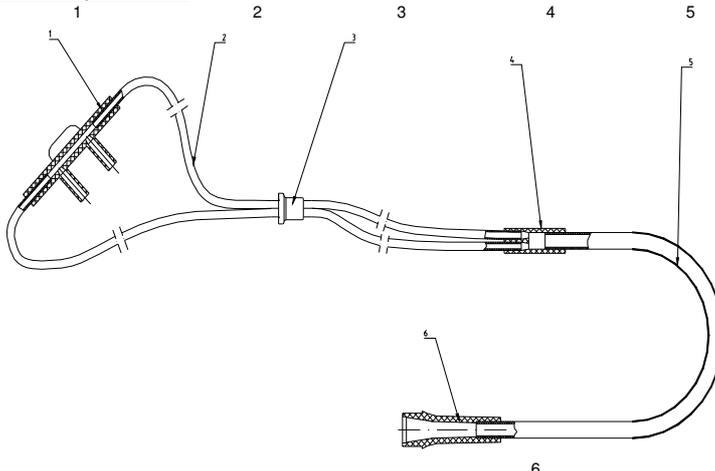


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**Drawing and Material specifications:**



Component	Material
1 Nasal cannula with nostril tips	PVC (Polyvinyl chloride polymer)
2 oxygen tubes	PVC (Polyvinyl chloride polymer)
3 Casing / Fixation ring	ABS (Acrylonitrile Butadiene Styrene)
4 Y-shaped tube	PVC (Polyvinyl chloride polymer)
5 oxygen supply tube	PVC (Polyvinyl chloride polymer)
6 oxygen supply connector	PVC (Polyvinyl chloride polymer)

Article no	Specification	Length of tube (cm)	Inner diameter of the oxygen supply tube in mm	Inner diameter of the oxygen tubes in mm	Length of the nostril tips in mm	Max pressure that can be applied/ max O2 flow
<b>B200516A</b>	Adult, green	210	Max. 4.6±0.1, Min. 3.9±0.1	Max. 2.4±0.1, Min. 1.9±0.1	11.5±1	50 kPa
<b>B201216A</b>	Pediatric, green	210	Max. 4.6±0.1, Min. 3.9±0.1	Max. 2.4±0.1, Min. 1.9±0.1	10±1	50 kPa

**Performance:** 50 kPa air pressure for 15 sec without leakage  
 static axial tension of 15 N for 15 sec without any damage

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

**Latex:** BEROTUBE oxygen cannula (tube) is latex-free

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

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- Storage:** Do not store at extreme temperatures. Keep away from moisture and direct sunlight.
- Disposal:** Used products are to be discarded in accordance with national and institutional guidelines.
- Precautions for use:** The operators should be professionally trained medical staff.
- Do not re-sterilize.
- Check the integrity of the individual package before use. Do not use if the package is damaged.
- To be used immediately when the individual package is opened.
- Discard after single use in accordance with national and institutional guidelines 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 materials the product consists of.
- Do not re-use. 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.

**Packing data:**

	pieces
individual plastic package	1
Export carton	250

**Variants:**

BEROTUBE sterile oxygen cannula (tube) for single use		
Article no	Specification	Length of tube (cm)
B200516A	Adult, green	210
B201216A	Pediatric, green	210

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