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

Summary Essential Technical Data - Sterile Nebulizers for single use

Manufacturer: Beromed GmbH Hospital Products
Kronenstrasse 19
10117 Berlin
GERMANY

Product: Nebulizers
(Sterile Nebulizers for single use)

Brand: BERONEB

UMDNS code: 12-712

Risk Class: IIa according to Annex IX, rule 2 of Council Directive 93/42/EEC,
as amended by Council Directive 2007/47/EC

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

Brief description of the product

BERONEB nebulizers are intended for nebulizing liquid medicine so that its aerosol can be inhaled and administered via the lungs.

This method of application is particularly suitable in cases of respiratory and / or pulmonary diseases such as infections or asthma.

BERONEB nebulizers are intended for short-term use.

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



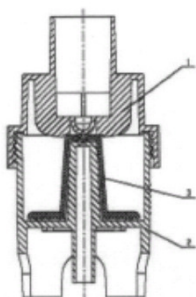
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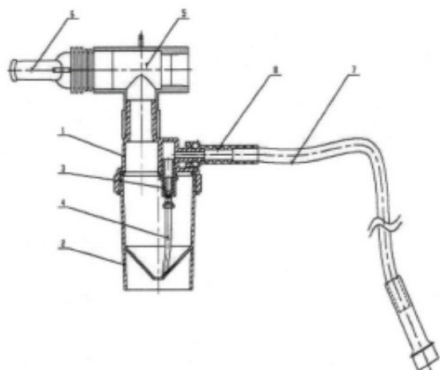
The following variants are available:

Nebulizer, 6 ml



- 1: Cap
- 2: Jar
- 3: Middle cap

Nebulizer, 20 ml



- 1: Cap
- 2: Jar
- 3: Jet tube
- 4: small tube
- 5: T-piece
- 6: Mouth-piece
- 7: Oxygen supply tube
- 8: Oxygen supply tube connector

mouth piece and "T"-piece providing connection to the patient



Nebulizers with Aerosol mask and tube



Mask dimensions	L x W x H mask	Length of oxygen tube / O.D / I.D.
adult standard	105 x 85 x 60 mm	2130 ± 50 mm / 5.6 ± 0.1 mm / 3.0 ± 0.2 mm
adult elongated	130 x 85 x 65 mm	
paediatric standard	75 x 70 x 45 mm	
paediatric elongated	95 x 70 x 50 mm	

(length and width ± 10 mm, height ± 5 mm)

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Material specification:

Components/construction:

Type	components	
6 ml	T-piece, mouth piece, oxygen supply tube, oxygen supply tube connector	cap, middle cap, jar
20 ml		jet tube, cap, jar, small tube

Material specification:

Nebulizer 6 ml:

Component	Material	
Cap	Polypropylene (PP)	
Middle Cap	Polypropylene (PP)	
Jar	Polycarbonate (PC)	
T-piece	Acrylonitrile Butadiene Styrene (ABS)	
Mouth piece	High-density Polyethylene (HDPE)	
Oxygen supply tube	Polyvinylchloride (PVC)	<i>plasticizer used for PVC: DOP (DEHP)</i>
Oxygen supply tube connector	Polyvinylchloride (PVC)	

Nebulizer 20 ml:

Component	Material	
Cap	High-density Polyethylene (HDPE)	
Jar	Polypropylene (PP)	
Jet tube	Acrylonitrile Butadiene Styrene (ABS)	
Small tube	Polypropylene (PP)	
T-piece	Acrylonitrile Butadiene Styrene (ABS)	
Mouth piece	High-density Polyethylene (HDPE)	
Oxygen supply tube	Polyvinylchloride (PVC)	<i>plasticizer used for PVC: DOP (DEHP)</i>
Oxygen supply tube connector	Polyvinylchloride (PVC)	

Aerosol mask (if applicable)	PVC, aluminium
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Sterilization: by ethylene oxide (EO)

Shelf life: 5 years from the date of manufacture

Latex: BERONEB nebulizers are latex-free

Storage: Do not store at extreme temperature and humidity.

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:

	Quantity per (pieces)	Dimensions (m)
Individual package (Pouch)	1	0,085 x 0,125
Export carton	50	0,50 x 0,290 x 0,260

Variants:

BERONEB, sterile Nebulizers for single use

Article no	Specification
B264266	Nebulizer, jar of 6 ml
B264273	Nebulizer, jar of 20 ml
B264280	Nebulizer, mouth piece
B264297	Nebulizer with aerosol mask, 6 ml jar (adult standard)
B264303	Nebulizer with aerosol mask, 6 ml jar (adult elongated)
B264310	Nebulizer with aerosol mask, 6 ml jar (pediatric standard)
B264327	Nebulizer with aerosol mask, 6 ml jar (pediatric elongated)
B264334	Nebulizer with aerosol mask, 20 ml jar (adult standard)
B264341	Nebulizer with aerosol mask, 20 ml jar (adult elongated)
B264358	Nebulizer with aerosol mask, 20 ml jar (pediatric standard)
B264365	Nebulizer with aerosol mask, 20 ml jar (pediatric elongated)
B264372	Nebulizer with mouth piece, 6 ml jar
B264389	Nebulizer with mouth piece, 20 ml jar

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