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

Summary essential technical data - *BEROTUBE* sterile stomach tube for single use

Manufacturer: Beromed GmbH Hospital Products
 Kronenstrasse 19
 10117 Berlin
 GERMANY

Product: Stomach Tube

Brand: *BEROTUBE*®

UMDNS code: 14-199

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 excluding (4) 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

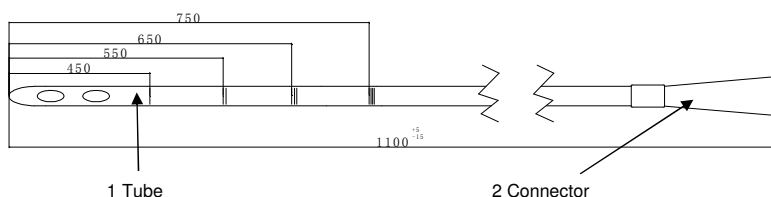
Brief description of the product

BEROTUBE stomach tube is a medical device used to provide (gastroenteral) nutrition to patients who temporarily cannot obtain nutrition by swallowing, e.g. after surgical procedures.

The product is intended for short-term use.

BEROTUBE is sterile and intended for single use on a single patient only.

Drawing and Material specifications:



Component	Material
1 Tube	Polyvinyl chloride polymer (PVC)
2 Connector	Polyvinyl chloride polymer (PVC)

Features: soft, frosted and kink-resistant PVC
 atraumatic soft and rounded open tip
 two lateral eyes



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- Sterilization:** by Ethylene Oxide (EO)
- Latex:** *BEROTUBE* stomach tube is latex-free
- Shelf life:** 5 years from the date of manufacture
dates of manufacture and expiry are printed on the individual package
- Storage:** Store in a clean and dry place. Store away from direct sunlight. Do not store at extreme temperatures.
- Disposal:** Discard the product after single use in accordance with pertinent national and institutional guidelines for biohazardous waste.
- Precautions for use:**
- Use is restricted to qualified healthcare professionals.
- Check the integrity of the individual package before use.
- Do not use if the package is damaged.
- To be used immediately after the individual package has been opened.
- Do not use after the expiry date.
- 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.

Packing data:

	pieces
individual package	1
Inner box	50
Export carton	200

Variants:

BEROTUBE, Stomach tube		
Article no	Size (CH)	Length of tube (cm)
B201032A	08	110
B201049A	10	110
B200158A	12	110
B200165A	14	110
B200172A	16	110
B200189A	18	110
B200196A	20	110
B200202A	22	110
B201056A	24	110
B200219A	25	110
B203920A	26	110
B200226A	28	110
B200233A	30	110
B200240A	32	110

Bank Deutsche Bank AG, Berlin
Bank Code 100 700 00
Account No. 605 37 55 00
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905 83 45 00
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