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

Summary essential technical data - *BEROTUBE* - Sterile rectal catheter (tube) for single use

Manufacturer: Beromed GmbH Hospital Products
Kronenstrasse 19
10117 Berlin
GERMANY

Product: Rectal Catheter (tube)

Brand: *BEROTUBE*

UMDNS code: 14-227

Risk Class: Is 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 V 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 rectal catheter (tube) is a medical device intended for the irrigation of rectum and intestinum prior to surgical operations or ante partum.

BEROTUBE is sterile and intended for single use only.

Bank	Deutsche Bank AG, Berlin
Bank Code	100 700 00
Account No.	605 37 55 00
IBAN	DE05 1007 0000 0605 3755 00
SWIFT	DEUT DE 33

Commerzbank AG, Berlin
100 800 00
905 83 45 00
DE75 1008 0000 0905 8345 00
DRES DE 33 100

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

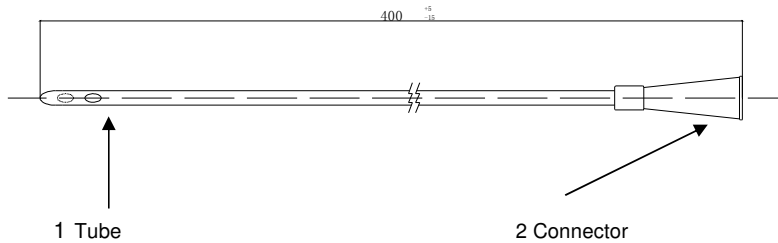


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Drawing and Material specifications:



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

Features:

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

Sterilization:

by Ethylene Oxide (EO)

Latex:

BEROTUBE rectal catheter (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:

Do not store at extreme temperatures and humidity.

Precautions for use:

The operators should be professionally trained medical staff.

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

For single use only. To be used immediately when individual package is opened.

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.

Do not re-sterilize.

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.



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Packing data:

	pieces
individual packing (paper-plastic package)	1
Inner box	50
Export carton	300

Variants:

BEROTUBE- Rectal Catheter (tube), 40 cm

Article no	Size (CH)
B201537A	12
B201544A	14
B201551A	16
B200141A	18
B201278A	20
B201285A	22
B201292A	24
B201568A	25
B201308A	26
B201315A	28
B201322A	30
B201575A	32
B201582A	34
B201650A	36

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