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Summary Essential Technical Data - Urine Bags for single use, non-sterile

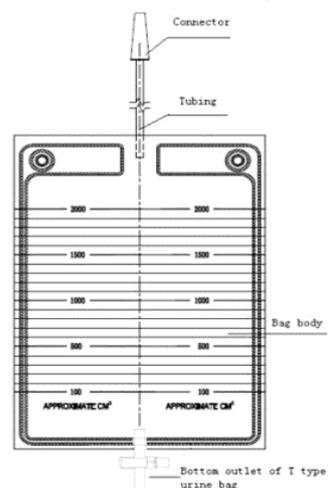
Manufacturer:	Beromed GmbH Hospital Products Kronenstrasse 19 10117 Berlin GERMANY
Product:	Urine bags, non-sterile
UMDNS code:	14-298
Risk Class:	I according to Annex IX of Council Directive 93/42/EEC, as amended by Council Directive 2007/47/EC
Conformity assessment procedure:	according to Annex VII of Council Directive 93/42/EEC, as amended by Council Directive 2007/47/EC

Brief description of the product

Urine bags for single use are intended for the collection of urine in connection with urethral catheters. They are used for patients unable of micturition and for incontinent or bed-ridden persons.

Beromed urine bag REF B202657A has a nominal capacity of 2000 ml and is equipped with a non-return valve and cross outlet (T-type).

Drawing:



Bag body size (mm): L: 190 ± 5, H: 300 ± 5; Bag body thickness (mm): ≥ 0.2

Material specifications:

Component	Material
Bottom outlet	Polyvinyl chloride polymer (PVC)
Preventive cap for outlet	Polyethylene (PE)
Non-return valve	Polyvinyl chloride polymer (PVC)
Tubing	Polyvinyl chloride polymer (PVC)
Bag	Polyvinyl chloride polymer (PVC)
Connector	Polyethylene (PE)
Preventive cap for connector	Polypropylene (PP)

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 BB

Commerzbank AG, Berlin
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905 83 45 00
DE75 1008 0000 0905 8345 00
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Registered Office: Berlin
Managing Director: Jörg Bartz
Commercial Registry: Berlin-Charlottenburg HRB 65718
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Shelf life: 5 years from the date of manufacture

Latex: Beromed Urine bags are latex-free.

Storage: Store in a clean and dry place. Avoid excessive heat, protect from direct sunlight and moisture.

Precautions for use: Use is restricted to qualified healthcare professionals.

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. Do not recycle or reprocess.

Packing data:

Packing unit	Quantity per packing unit (pcs)
Middle plastic bag	25
Export carton	300

Specification:

Non-sterile urine bags for single use

Article no	Length of tube (cm)	Bag size in ml	Outlet
B202657A	90	2000	with cross outlet (T-type) and non-return valve

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