

BEDPAN TECHNICAL SPECIFICATION

Definition

- Device for the faeces and urine collection.

General features

- It's a device indicated for the faeces collection, used for patients in bed or with some problems to use the toilette. In plastic material, with an anatomical handle, resistant up to 140 kg.
After each use it's advisable to carefully clean the device with water and soap and sanitize.
Sterilizable in autoclave at ETO or at cold.
- It's also available the Badpan cover.



Applications

- Indicate for the faeces collection.



**Medical device according to the directive CEE 93/42
modified by the directive 2007/47/CE
Implementation with D.L n°37 of the 25/01/2010**

Class I

- Use: Not invasive Medical device.

Conformity

- Quality Assurance System: certified according to UNI EN ISO 9001:2008.

Technical specifications

Product RAW MATERIAL	White Polypropilene
Pack RAW MATERIAL	Single pack in transparent bag

Sterile	No
Latex in the product	No
Latex in the bag	No
Storage condition	Store in a cold dry place away from heat sources

Possibility of sterilization

- Non sterile product.
- It can be sterilized in autoclave at ETO or at cold.



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Biocompatibility

- BIOCOMPATIBILITY TEST: cytotoxicity, sensitization and irritation.

Disposal

- In compliance with applicable laws.

Indications of use

- After each use carefully clean with water and soap

Quality control

- Each batch is controlled according to the internal procedures. Controls are made on incoming raw material and during the manufacturing process.
- Tests are made according to the methods for aestetical, visual and dimensional tests according to sampling system of the normative UNI ISO 2859.

Packaging

Labels and/or packages have the following:

Name
Manufacturer
Date and lot
Expiry date
Storage information
Item barcode

Packaging material

- Single pack in transparent bag

Manufacturer

- Artsana S.p.A. Via Saldarini Catelli 1, 22070 Grandate (Como) Italy.

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Assortment

Code	Pack	BOX
03 050070 100 000	1 pcs	30 pcs
03 050076 100 000	1 pcs	30 pcs

Additional information

- Additional information and operating procedures are included in the technical dossiers filed with ARTSANA's Technical/Quality Assurance department.

The Technical Department

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