

ENEMA ACCESSORIES: HOSE-TAP-CANNULATECHNICAL INFORMATION

Definition

- Enema accessories



General features

- This kit contains anal and vaginal canula, tube, connection and tap.

Applications

- Vaginal canula is used as terminal device for medical irrigations of the vaginal canal
- Anal canula is used for medical irrigations of the vaginal canal or for substances stimulating the intestinal activities
- The hose for enema is constituted by a central part that permits to block/unblock the flow and by a tube.

Medical device according to the directive CEE 93/42

Modified by the directive 2007/47/CE

Implementation with D.L. n°37 del 25-01-2010

Class I

Conformity

- DIRECTIVE CEE 93/42
- Quality Assurance System: certified according to ISO 9001.
- Quality Assurance System: certified according to ISO 13485.

Technical specification

CONTENTS	Anal Canula: external diameter max 15 mm, lenght 70 mm Vaginal canula: external diameter max 12 mm, lenght 143 mm
	Tap key: hight 33 mm, width 12 mm Tap body: hight 20 mm, width 15 mm, lenght 58
PACKAGING	The kit is packaged in a strong plastic closed again envelope

Sterile	No
Latex (in the product)	No
Latex (in the package)	No
Storage instructions	Store in a cool, dry place, away from heat and direct sunlight

Product sterilization

- No sterile product.

Biocompatibility

- BIOCOMPATIBILITY TEST: The product has successfully undergone the biocompatibility tests for cytotoxicity, sensitization and irritation.

Disposal

- In compliance with applicable laws. The product can be integrated with the hospital waste or special waste.



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Indications for use

- After each use carefully wash the device and its accessories and put it away only if total dry.

Quality control

- The product is tested according to a sampling system presented by UNI ISO 2859.

Packaging

Labels and/or packages have the following:

Product name
Manufacturer
Date and batch of production
Validity
Storage instruction
Item Bar code

Packaging material

- Packaged in transparent plastic envelope.

Manufacturer

- Pikkdare S.p.A. - Via Saldarini Catelli 10 - 22070 Casnate con Bernate (Como) - Italy

Assortment

Codice	Modello	Confezione	Imballo
02 050011 100 000	Accessories kit	1 pcs	150 pcs

Additional information

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

Technical director
 PIKDARE S.p.A.
 Dr. MAURO CASSANI
 Medical Devices Department
 Technical Director

