1. DEVICE DESCRIPTION

INSTYLAN – Solution for Intravesical Irrigation is a sterile solution based on hyaluronic acid designed for temporary protection and restoration of mucus membrane of urinary bladder. This medical device is a transparent and odorless solution contained in a Phtalates Free PVC plastic bag equipped with an irrigation tube and connector. Each PVC bag is packed in individual plastic vacuum bag. The irrigation to the patient is made by urological catheter.

DIACO BIOFARMACETICI SRL produces 1 different line of Solution for Intravesical Irrigation:

Medical devices manufactured by DIACO BIOFARMACETICI SRL are manufactured in the following product ranges:

ISTYLAN 0.16%

- 50 ML of Sterile solution based on hyaluronic acid for intravesical irrigation contained in disposable plastic bags with 0,16% of Hyaluronic Acid (80mg/50ml);

The disposable bag is pre-filled with the solution and sterilized by steam sterilization. The sterilization process is validated according the reference standard (ISO 17655). Protocol and report of sterilization is attached as section TFIN-10.

2. COMPOSITION

CAS Number	Formula	Source	Nomenclature	Specification	Function	Common Name	%
7732-18-5	H_2O	Yuria-pharm Ltd	Water for injections in bulk	SP-08.03.-069	Solvent	Water	98,96085
9067-32-7	$(C_{14}H_{20}NNaO_{11})_n$	Contipro Biotech	Sodium Hyaluronate	SP-07.01MD-009	Basic component	Sodium Hyaluronate	0.16
13472-35-0	NaH_2PO_4	Sigma Aldrich	Sodium dihydrogen phosphate dihydrate	SP-07.01-093c	pH Buffer	Sodium dihydrogen phosphate dihydrate	0.00395
7558-79-4	Na_2HPO_4	Sigma Aldrich	Disodium phosphate, anhydrous	SP-07.01-094c	pH Buffer	Disodium phosphate, anhydrous	0.0276
7647-14-5	NaCl	Salinen	Sodium Chloride	SP-07.01-027	Osmolality Adjustment	Sodium Chloride	0.8476

The solution described above is contained in a plastic bag equipped with an irrigation tube and connector. Technical specification for packaging material is described in section TFIN-09 (Component Specifications)

3. INTENDED USE

INSTYLAN is intended for irrigation into bladder cavity using urological catheter. The irrigation of this medical device provides the formation of a viscous elastic film on the surface of mucous layer of the bladder:

- protecting it from external effects during various surgeries (ureteroscopy, cystoscopy, transurethral resection of adenoma and radiation therapy of lesser pelvis organs etc);
- protecting it from harmful impact of bladder content (urina) in case of injury or inflammation of mucous layer of the bladder;

Then, thanks to the formation of a viscous elastic film on the surface of bladder mucous layer the bladder is preserved form external effects during various surgeries and in case of injury or inflammation of mucous layer of the bladder.

Mechanism of action.

INSTYLAN – Solution for Intravesical Irrigation based on hyaluronic acid provides the formation of a viscous elastic film on the surface of bladder mucous layer for protecting it from external effects during various types of surgeries (urethra cystoscopy, radiation therapy etc), by irrigation into the bladder cavity.

Medical application field:

- Urology

All the products described in this Technical File are intended to be used only by doctors in a medical fild. The irrigation into bladder must be provided by a trained medical specialist in specialized premise with appropriate equipment and aseptic conditions.

Furthermore, according with European Directive 2007/47/CE, that modifies European Directive 93/42/CEE, DIACO BIOFARMACEUTICI SRL declares that the products described in this technical file:

1. don't contain a human blood derivative as per point 7.4 of Annex I of European Directive 2007/47/CE;

2. don't contain any animal tissues or their derivatives as per point 8.2 of Annex I of European Directive 2007/47/CE;

3. don't incorporate, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in Article 1 of Directive 2001/83/EC and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified, by analogy with the methods specified in Annex 1 to Directive 2001/83/EEC;

4. DEVICE IDENTIFICATION

Medical device identification is specified in the following table:

IDENTIFICATION	DESCRIPTION
INSTYLAN 0.16%	50 ML of Sterile solution based on hyaluronic acid for intravesical irrigation contained in disposable plastic bags with 0,16% of Hyaluronic Acid (80mg/50ml);

5. MEDICAL DEVICE CLASSIFICATION (Annex IX, MDD 93/42/CEE)

Medical device "**INSTYLAN – sterile solution based on hyaluronic acid"**, described in this technical file, are classified as medical devices with risk class **IIa** according rule 5 Annex IX of Medical device Directive 93/42/CEE, modified by European Directive 2007/47/CE.

Medical device "**INSTYLAN – sterile solution based on hyaluronic acid"**, must be manufactured according Essential Requirements specified in Annex I and according to Annex V of Medical device Directive 93/42/CEE and subsequent modification.

Since Rule 5 of Annex IX of Medical device Directive 93/42/CEE and subsequent modification states:

"All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I;

- *are in Class I if they are intended for transient use,*
- *are in Class IIa if they are intended for short term use; except if they are used in the oral cavity as far as the pharynx, in an ear canalup to the ear drum or in a nasal cavity , in which case they are in Class I,*
- *are in Class IIb if they are intended for long term use,*
  except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa

Specifically:

Since the medical device treated in this technical file are intended ***for irrigation of the bladder***, we defined that our devices ***are in Class IIa*** according with its *short term use*.

6. DEVICE LIFE

Medical device "**INSTYLAN – sterile solution based on hyaluronic acid"**, are devices intended to be introduced into the human body through orifices and intended to remain in place not more then 30 days, they are considered for short term use.

Medical device "**INSTYLAN – sterile solution based on hyaluronic acid"** are sterile devices and the shelf life is guarantee for 24 months.

7. NOTIFIED BODY

Certification request is has been forwarded to the Notified Body n° 1936:

TUV Rheinland Italia S.r.l.

Via Mattei, 3

20010 Pogliano Milanese (MI)

Product certification will be done according to Annex V of Medical device Directive 93/42/CEE e subsequent modifications.

8. MANUFACTURER

Company name:	**DIACO BIOFARMACEUTICI SRL**
Company address:	Via Flavia 124, 34147 Trieste (TS)
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Sito internet:	http://www.diaco.it

The Company assures that all technical file documentation will stored at least for 10 years.