INSUMED
INSULIN SYRINGES IN PROTECTED VERSION
TECHNICAL INFORMATION

Definition

- Sterile insulin syringe. Disposable, pyrogen free and non-toxic in protected packaging
  Capacity: 0,3ml and 0,5ml and 1ml

General features

- Needle directly inserted in the syringe (No Dead Space).
- Easy to read, durable graduated scale.
- 0,3 ml: graduated scale with half unit
- 0,5 ml and 1ml: graduated scale with U-100
- Latex free gasket with a triple contact and flat form.
- Plunger-block device.
- Cover needle cap and cover piston cap have a saved guarantee sterility seal.
- Hight transparent polypropylene.
- Ethylene Oxide-sterilised.
- Pack of 30 syringes with optical detachable label.
- Magnifier to apply to the syringe for making easier the reading of the scale. One piece in each pack.

Applications

- Insulin therapy through subcutaneous injections.
- Adapt for mixing different kind of insulin.
- 0,3 ml: adapt in phaediatric field

CE 0373 LATEX FREE

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 II A

Conformity

EN ISO 7864	Dispsable sterile hypodermic needle
EN ISO 9626	Inox steel
EN ISO 8537	Disposable, sterile insulin syringes, with or without needle
ISO 2859	Sampling plan
ISO 11135	Sterilization
EN ISO 10993-1	Biocompatibility
Quality Assurance system:	certified according to ISO 9001
Quality Assurance system:	certified according to ISO 13485

PIKDARE

Rev. 01 del 03/08/2018

Pikdare S.r.l. - Via Saldarini Catelli 10 - 22070 Casnate con Bernate (CO) - Italy
Tel. 0039 031 7297111 - Fax 0039 031 7297100 - www.picsolution.com

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Technical specifications

COMPONENT	MATERIAL	CONFORMITY
Barrel	Polypropylene non-toxic for medical use	Directive 10/2011 CEE
Plunger	Polypropylene non-toxic for medical use	Directive 10/2011 CEE
GASKET	Latex free	Eur. Pharm In force
Silicon	D.C. 360 M.F. non-toxic and pyrogen free for medical use maximal quantity . 0,25 mg/cm2	Eur. Pharm – U.S.P. in force
Cannula	Inox Steel aisi 304	EN ISO 9626
Needle cover	Polyethylene non-toxic for a medical use	Directive 10/2011 CEE
GLUE	UV Glue – non-toxic	Directive ecc 91/155
Ink	Non-toxic specific for polypropylene	D.M. 21-03-73 and the following modifications
Protective end cap	Polyethylene	Directive 10/2011 CEE

Sterile	YES
Latex	NO
Expiry date	5 years from the production date in not damaged pack
Storage instructions	Store in a cool, dry place away from chemical substances

Product sterilization
- Gas Ethylene Oxide according to norm EN ISO 11135.

Biocompatibility
- The product has successfully undergone the biocompatibility tests required by EN ISO 10993, for cytotoxicity, Emocompatibility, sensitization, toxicity and skin reactivity tests.

Disposal
- In compliance with applicable laws.

Subdivision scale

ML.	U.I	SUBDIVISION MIN.	NORMS
0,3	30	U.I. 0,5	EN ISO 8537
0,5	50	U.I. 1	EN ISO 8537
1	100	U.I. 2	EN ISO 8537

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Productive process

- Integrated areas of high automation in CLEAN ROOMS of class 100.000 (ISO 8).

Quality control

- Quality controls in process 100% and with sampling plan according to ISO 2859 norm.

Packaging

Labels and/or packages have the following:

Product definition
CE Mark
Capacity/Concentration
Production's department
Method of sterilization
Expiry date
Storage instructions
Detachable label
Product Bar code
Batch Bar code

Packaging material

COMPONENT	MATERIAL	CONFORMITY
Bag (0,3-0,5ml-1ml)	Polyetylene	D.M. 21-03-73 and the following modifications
Box 30 pcs	Carton	G.I.F.C.O.
Package 1.200 pcs	Corrugated paper	G.I.F.C.O.

Manufacturer

- Pikdare S.r.l. Via Saldarini Catelli 10, 22070 Casnate con Bernate (Como) Italy

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Assortment

CODE	ML	NEEDLE	PACK	UNIT	CARTON
02 022725 030 150	0,3	31Gx8mm	Bag 10 pcs	3 Bags of 10 pcs	120 Bags of 10 pcs
02 022720 030 150	0,3	30Gx8mm	Bag 10 pcs	3 Bags of 10 pcs	120 Bags of 10 pcs
02 022722 050 150	0,5	31Gx8mm	Bag 10 pcs	3 Bags of 10 pcs	120 Bags of 10 pcs
02 022721 050 150	0,5	30Gx8mm	Bag 10 pcs	3 Bags of 10 pcs	120 Bags of 10 pcs
02 022723 050 150	0,5	29Gx12,7mm	Bag 10 pcs	3 Bags of 10 pcs	120 Bags of 10 pcs
02 022726 100 150	1	30Gx8mm	Bag 10 pcs	3 Bags of 10 pcs	120 Bags of 10 pcs
02 022727 100 150	1	30Gx12,7mm	Bag 10 pcs	3 Bags of 10 pcs	120 Bags of 10 pcs

Additional information

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

Direttore tecnico

PIKDARE S.R.L.
Dr. MAURO CASSANI
Medical Devices Department
Technical Director

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