



INSUPEN ORIGINAL

NEEDLE FOR INSULIN PEN

TECHNICAL INFORMATION

Definition

- Sterile needle for insulin pen.
Disposable, pyrogen free, non-toxic. In individual protective pack.

General features

- Needle with completely automated triple sharpening.
- Needle treated with silicone to ease penetration into skin and minimise discomfort.
- Anti-friction cartridge tip to ease perforation of insulin cartridge.
- Ethylene Oxide sterilised
- According to the norms EN ISO 11608-2



Applications

- Therapy of insulin through subcutaneous injections.



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 11608-2 Pen needle
- EN ISO 7864 Disposable hypodermic needle
- EN ISO 9626 Inox steel
- ISO 2859 Sampling plan
- EN ISO 11135 Sterilization
- EN ISO 10993-1 Biocompatibility
- Quality Assurance system: certified according to ISO 9001
- Quality Assurance system: certified according to ISO 13485

Technical specifications

COMPONENT	MATERIAL	CONFORMITY
Inner and outer cap	Non-toxic polyethylene	Directive 10/2011 CEE
Hub	Non-toxic polypropylene	Directive 10/2011 CEE
Cannula	Inox steel	ISO 9626
Silicon	Non-toxic and pyrogen free for medical use	Eur. Ph. – U.S.P. in force
Needle cover	Non-toxic polyethylene	Directive 10/2011 CEE
Glue	Non-toxic UV glue	Directive 10/2011 CEE



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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 at 10% according to norm EN ISO 11135.

Biocompatibilità

TEST	CONFORMITY
Cytotoxicity	ISO 10993-5
Intracutaneous reactivity	ISO 10993-10
Acute systemic toxicity	ISO 10993-11
Allergic sensitization	ISO 10993-10
Hemolysis of direct and indirect contact	ISO 10993-4

Disposal

- In compliance with applicable laws.

Productive process

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

Quality control

- Quality controls in process (100% of the production through IPC) and with sampling plan on non-sterile semifinished product and sterile product.

Packaging

Labels and/or packages have the following:

Product definition
CE Mark
Diameter / Needle Length
Production department
Method of sterilization
Expiry date
Storage instructions
Detachable label
Product Bar code
Batch Bar code

Packaging material:

COMPONENT	MATERIAL	CONFORMITY
SEALING PAPER	Medical paper	F.D.A. (sez.21-CFR176-170)
BOX	Carton	G.I.F.C.O.
PACKAGE	Cartone ondulato	G.I.F.C.O.





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Manufacturer

➤ Pikdare S.p.A. – Via Saldarini Catelli 10 – 22070 Casnate con Bernate (Como) – Italy

Assortment

REF.	NEEDLE MEASURE	DIAMETER	LENGHT	WALL	UNIT	CARTON
02022988000030	G29	0,33 mm	12mm	Regular Wall	100 pcs	1.200 pcs
02022987000030	G30	0,30 mm	8mm	Regular Wall	100 pcs	1.200 pcs
02022902000030	G31	0,25 mm	5mm	Extra Thin Wall	100 pcs	1.200 pcs
02022989000030	G31	0,25 mm	6mm	Extra Thin Wall	100 pcs	1.200 pcs
02022990000030	G31	0,25 mm	8mm	Extra Thin Wall	100 pcs	1.200 pcs
02002262000000	G32	0,23 mm	4mm	Extra Thin Wall	100 pcs	1.200 pcs
02022983000030	G32	0,23 mm	6mm	Thin Wall	100 pcs	1.200 pcs
02022984000030	G32	0,23 mm	8mm	Thin Wall	100 pcs	1.200 pcs
02002264000000	G33	0,20 mm	4mm	Thin Wall	100 pcs	1.200 pcs

Additional information

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

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

