STERILE SYRINGE WITH TUBERCOLIN NEEDLE
TECHNICAL INFORMATION

Definition

- Disposable, pyrogen free, non-toxic, sterile syringe with needle.

General features

- Rubber piston Latex Free.
- High transparency polypropylene.
- Easy to read and stable graduated scale.
- Needle with triple sharpening.
- Stop device of the piston
- "Peel-Pack" single blister.

CE 0373

Applications

- Subcutaneous, intramuscular injection of small volumes.

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

- ISO 7886–1 Disposable sterile syringe
- ISO 9626 Tubes for stainless steel needles for the production of medical device
- ISO 7864 Disposable hypodermic needle
- ISO 6009 Codification of colour identification
- ISO 2859 Sampling plan
- ISO 80369-7 Connector for hypodermic application
- ISO 11135 Sterilization
- ISO 10993 Biocompatibility
- Quality Assurance system: according to ISO 9001
- Quality Assurance system: according to ISO 13485

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Technical specifications

COMPONENT	MATERIAL	CONFORMITY
Cilinder	non-toxic Polypropylene	Directive 10/2011 CEE
Piston	Polypropylene	Directive 10/2011 CEE
Rubber gasket	Latex free	F.E. in force
Silicon	Non-toxic and pyrogen free for medical use Q.ty max 0,25 mg/cm2	F.E. / U.S.P. in force
Hub	non-toxic Polypropylene	Directive 10/2011 CEE
Cannula	Stainless steel AISI 304	ISO 9626
Needle cover	non-toxic Polypropylene	Directive 10/2011 CEE
Glue	non-toxic Epossidic glue	Directive 10/2011 CEE
Ink	Non-toxic specific for polypropylene	D.M.21-03-73 and following modifications

Sterile	YES
Latex	NO
Expiry date	5 years from the production date in intact pack
Storage instructions	Store in a cool, dry place away from chemical substances

Scale subdivision

U.M.	Nominal capacity	Graduation up to	Subdivision min.	Norms
ml.	1	1	0,01	ISO 7886-1

Product sterilization

- Gas Ethylene Oxide according to norm ISO 11135

Biocompatibility

- The product has successfully undergone the biocompatibility tests required by ISO 10993, for cytotoxicity, emocompatibility, sensitization, toxicity and skin reactivity test

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% and with sampling plan according to ISO 2859

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Packaging

Labels and/or packages have the following:

Product definition
CE Mark
Dimension
Manufacturer
Method of sterilization
Expiry date
Storage instructions
Product Bar code
Batch Bar code

Packaging material

Component	Material	Conformity
Single Blister	Medical paper	F.D.A. (sez.21-CFR176-170)
	Film plastico in PE+PP+PA	D.M. 21-03-73 and following modifications
Box	Corrugated paper	G.I.F.C.O.
Package	Corrugated paper	G.I.F.C.O.

Manufacturer

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

Assortment

CODE	DESCRIPTION	ML	NEEDLE	UNIT	CARTON
02071260300320	PIC TUBERCOLIN SYRINGE 1ML G26X1/2''	1ml	0.45X13mm	100 pcs	800 pcs
02071270300320	PIC TUBERCOLIN SYRINGE 1ML G27X1/2''	1ml	0.4X13mm	100 pcs	800 pcs

Technical director

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Dr. MAURO CASSANI
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Technical Director

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