

# STERILE MESOTHERAPY NEEDLES TECHNICAL INFORMATION

## **Definition**

- Sterile, pyrogen free, disposable, non-toxic needle.



## **General features**

- Luer Lock hub.
- Individual "Peel-Open" blister.
- Triple sharpening with anti-coring treatment.
- Ultra sound washing system.
- Anti- friction silicone treatment.
- International color coded.



## **Applications**

- For intradermic injections, especially during mesotherapy treatments and microinjections.

**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 7864 Hypodermic disposable needle
- ISO 9626 Needles and tubes for medical instruments
- ISO 80369-7 Connectors for hypodermic application
- ISO 6009 Colour identification's code
- ISO 2859 Sampling plan
- ISO 11135 Sterilization
- ISO 10993 Biocompatibility
- Quality Assurance system: certified according to ISO 9001
- Quality Assurance system: certified according to ISO 13485

## **Technical specifications**

COMPONENT	MATERIAL	CONFORMITY
Hub	Polypropylene non toxic	Directive 10/2011 CEE
Canula	Stainless steel AISI 304-304L	ISO 9626
Shield	Polypropylene non toxic	Directive 10/2011 CEE
Glue	Epoxy glue - non-toxic	Directive 10/2011 CEE
Colourant		D.M. 21-03-73 and the following modifications
Silicon	non toxic, pyrogen free, for medical use - cantidad max 0,25 mg/cm2	F.E. / U.S.P. in force



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

## 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 norm

## 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. (section 21-CFR176-170)
	Film plastico in PE+PP+PA	D.M. 21-03-73 and following modifications
Box	Glazed paper	G.I.F.C.O.
Package	Corrugated paper	G.I.F.C.O.

2/3

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# STERILE MESOTHERAPY NEEDLES TECHNICAL INFORMATION

## Manufacturer

➤ Pikkdare S.r.l Via Saldarini Catelli 10, 22070 Casnate con Bernate Como - Italy

## Assortment

CODE	DESCRIPTION	COLOUR	GAUGE	NEEDLE	UNIT	CARTON
02070994300800	PIC MESOTHERAPY NEEDLE G27X4mm	GRAY	G27	0,40x4mm	100 pcs	4.000 pcs
02070996300800	PIC MESOTHERAPY NEEDLE G27X6mm	GRAY	G27	0,40x6mm	100 pcs	4.000 pcs

**Technical Director**

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

3/3

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