



STERILE MESOTHERAPY NEEDLES TECHNICAL INFORMATION

Definition

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

General features

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



Applications

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

Medical device: directive CEE 93/42 **Implementation with D.L. n°46 del 24-02-97**

Class II A

Conformity

- ISO 594-1 Conical Luer hub 6%
- ISO 7864 Hypodermic disposable needle
- ISO 9626 Needles and tubes for medical instruments
- ISO 683/13 Inox steel
- ISO 6009 Colour identification's code
- ISO 2859 Sampling plan
- EN 550 Sterilization
- ISO 10993 Biocompatibility
- Quality Assurance system: certified according to UNI EN ISO 9001:2000
- Quality Assurance system: certified according to UNI EN ISO 13485:2004





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Technical specifications

COMPONENT	MATERIAL	CONFORMITY
Hub	Polypropylene non toxic for medical use	Directive 72/2002 CEE
Shield	Polyethylene non toxic for medical use	Directive 72/2002 CEE
Cannula	Inox steel AISI 304-304L	ISO 683/13
Silicon	D.C. 360 M.F. non toxic, pyrogen free, for medical use.	F.E. / U.S.P. in force
Colourant		D.M. 21-03-73 and the following modifications

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 UNI EN 550

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 UNI ISO 2859 norm



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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)
	Thermoformed bowl in coupled PP+LDPE	D.M. 21-03-73 and the following modifications
Box	Corrugated paper	G.I.F.C.O.
Package	Corrugated paper	G.I.F.C.O.

Manufacturer

➤ Artsana S.p.A Grandate Como Italy

Assortment

CODE	DIAMETER	LENGTH	UNIT	CARTON
03 070994 300 800	G27 – mm.0,40	mm. 4	100 pcs.	4.000 pcs.
03 070996 300 800	G27 – mm.0,40	mm. 6	100 pcs.	4.000 pcs.



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Additional information

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

The Technical Department

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