

STERILE LARGE VOLUME SYRINGES TECHNICAL INFORMATION

Definition

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

General features

- Triple contact rubber gasket.
- Eccentric Luer or Catheter hub.
- Individual "Peel-Open" blister.
- Highly transparent Polypropylene.
- Easy to read, durable graduated scale.
- Plunger-block device.



Applications

Administration, infusion of solutions.

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 594-1 Conic Luer hub 6%
- UNI EN ISO 10555-5 Catheter hub
- ISO 7886 Disposable sterile syringe
- ISO 2859 Sampling plan
- EN ISO 11135-1 Sterilization
- ISO 10993 Biocompatibility
- Quality Assurance System: according to UNI EN ISO 9001:2008
- Quality Assurance System: according to EN ISO 13485:2012

Technical specification

COMPONENT	MATERIAL	CONFORMITY
Barrel	Polypropylene non-toxic medical use	Directive 10/2011 CEE
Plunger	Polypropylene non-toxic medical use	Directive 10/2011 CEE
Gasket	Latex free	FU/FE in force
Silicon	D.C. 360 M.F. non-toxic and pyrogen free for medical use Q.ty max 0,25 mg/cm ²	FE / U.S.P. in force
Ink	Non toxic specific for polypropylene	D.M. 21-03-73 and the following modifications



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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

Scale subdivision:

U.M.	Nominal Volume	Graduation up to	Subdivision min.	Norms
ml.	30	35	1	ISO 7886/1
ml.	50	60	1	ISO 7886/1
ml.	100	100	2	ISO 7886/1

Product sterilization

- Gas Ethylene Oxide according to norm EN ISO 11135-1

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

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



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Packaging material

Component	Material	Conformity
Single Blister	Medical paper	F.D.A(sez.21-CFR176-170)
	Thermoformed bowl in couplet with 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 Via Saldarini Catelli 1, 22070 Grandate Como Italy

Assortment

CODE	ML.	HUB	UNIT	CARTON
03 078000 090 510	30	Eccentric Luer	50 pcs.	200 pcs.
03 078000 090 500	30	LUER LOCK	50 pcs.	200 pcs.
03 079000 090 510	50	Eccentric Luer	50 pcs.	300 pcs.
03 079003 090 500	50	Catheter	50 pcs.	300 pcs.
03 079007 090 300	100	Catheter (*)	25 pcs.	100 pcs.
03 079002 090 500	50	Luer Lock	50 pcs	300 pcs

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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