SCALP-VEIN NEEDLES
MIRAGE
TECHNICAL INFORMATION

Definition

- Sterile, disposable, pyrogen free, non-toxic scalp-vein needles

General features

- Thin wall scalp-vein needle
- Tube of 300 mm.
- Residual volume of the tube 0,44 ml
- Rigid Luer Lock connector
- "Peel-Pack" single blister
- Triple needle's sharpening with anti-coring treatment
- Ultrasound cannula washing system
- Siliconic treatment anti friction
- International colour coding

CE 0123 LATEX

Applications

- Peripheral venous access for a therapeutic purpose/sampling of biological material for diagnostic purpose.

Medical device: directive CEE 93/42
Modified by directive 47/2007/CE
Implementation with D.L. n°37 del 25-01-2010

Class II A

Conformity

- F.U/F.E in force
- ISO 9626 Tubes for stainless steel needle, to manufacture medical device
- ISO 6009 Codifica colori di identificazione
- ISO 11135 ETO sterilization
- EN 868-7 Packaging for sterilized medical devices - Part 7: adhesive paper for low temperature
- sterilization process – Requirements and test method
- ISO 10993 Biocompatibility
- ISO 2859 Sampling plan
- Quality Assurance system: certified according to ISO 9001
- Quality Assurance system: certified according to ISO 13485

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Technical specification

COMPONENT	MATERIAL	CONFORMITY
Butterfly	Non-toxic PVC for medical use	ISO 10993
Tube	Non-toxic PVC for medical use	ISO 10993
Connector Luer Lock	Non-toxic ABS for medical use	ISO 10993
Cap	Non-toxic PP for medical use	ISO 10993
Needle cover	Non-toxic polypropylene for medical use	
Cannula	Stainless steel AISI 304	ISO 9626
Silicon	Non-toxic and pyrogen free silicon for medical use	F.E. / U.S.P. in force
Glue	Epossidic glue	
Tube wrapping band	Non-toxic PE for medical use	

Sterile	YES
Latex	NO
Phtalate	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 ISO 11135

Biocompatibility

- Citotoxicity, intracutaneous reactivity, acute systemic toxicity, allergic sensitization, hemocompatibility, according to ISO 10993

Disposal

- In compliance with applicable laws

Quality control

- Quality control in process and on finished product according to ISO 2859

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Packaging

Labels and/or packages have the following:

Product definition
CE mark
Dimension
Tube residual volume
Manufacturer
EC rep
Method of sterilization
Expiry date
Storage instruction
Product Bar code
Batch Bar code

Packaging material:

Component	Material	Standard
Single blister	Medical paper	EN 868-7
	Film in LDPE	EN 868-7
Box	Carton	Na
Package	Corrugated carton	Na

Manufacturer

- Zhejiang Kindly Medical Devices Co., Ltd

Assortment

CODE	COLOUR	DIAMETER	LENGHT	UNIT	BOX
02044019030010	Amber	G19 – mm 1,10	3/4" - mm 19	100 pcs	1.000 pcs
02044020030010	Yellow	G20 – mm 0,90	3/4" - mm 19	100 pcs	1.000 pcs
02044021030010	Green	G21 – mm 0,80	3/4" - mm 19	100 pcs	1.000 pcs
02044022030010	Black	G22 – mm 0,70	3/4" - mm 19	100 pcs	1.000 pcs
02044023030010	Light blue	G23 – mm 0,60	3/4" - mm 19	100 pcs	1.000 pcs
02044025030010	orange	G25 – mm 0,50	3/4" - mm 19	100 pcs	1.000 pcs

Technical director

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