

DEHP FREE
NO LATEX

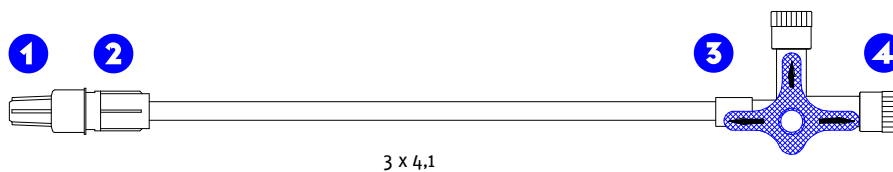


ACCESSORIES

Effe Emme[®]
FABBRICAZIONI MEDICALI



Code	FM code	Length mm
PL PDF100RB	LIB52	100
PL PDF150RB	LIB42	150
PL PDF250RB	LIB70	250
PL PDF500RB	LIB53	500
PL PDF750RB	LIB66	750
PL PDF1000RB	LIB54	1000
PL PDF1500RB	LIB65	1500



- 1 Vented cap** made of PE.
- 2 Male luer lock connector** made of ABS.
- 3 Blue Stopcock** 360° rotating diverter, made of PC.
- 4 Cap** made of PP.

Tubing is made of DEHP-FREE PVC.
(Tubing Lengths expressed in mm.)

CE risk class : IIa

Certification Body:

F.M. S.p.A. is TÜV SÜD certified, both for the CE (CE0123) mark, and the UNI EN ISO 9001/ISO 13485 standard.

Environment and Production Process:

The assembly is made in a 100.000 class clean room. Each material is tested for biocompatibility according to ISO 10993 standard.

Packaging:

Blister made of 2 different materials: plastic film and medical - grade paper

Box size: cm. 37 x 30 x 26 h.

Packaging Unit: 100 pcs. / box

Easy and safe opening of boxes, through a tab, to avoid the usage of cutters.

Storage and Use:

The circuit sterility is assured in a free from breakage package. To be used immediately after having removed the caps. The expiry date refers to the product in unopened and properly stored package. Recommended storage temperature: from 0 ° to + 40 °C.

Sterilization:

Sterile by EO.

Process according to UNI EN ISO 11135, EN 556. Sterility guaranteed for 5 years. Not to be resterilized.

Product Shelf Life: 5 years from date of manufacture.

Compliance:

Standard applicable to the product: ISO 13485, ISO 10993, ISO 11135, EN 20594, ISO 11607, EN 1041, EN ISO 14971.

Produced by:

F.M. S.p.A.
Via Farini, 65 bis
13043 CIGLIANO (VC)
ITALY

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