



Blood tubing made of Soft PVC

Pump segment 8 x 12 x 350 made of Soft PVC with high mechanical resistance

Heparine line 0,9 x 2 x 800

Service lines 3,5 x 5,5 x 90

- 1** PVC LATEX FREE injection sites without service line.
- 2** PVC Transducer Protector with PTFE hydrophobic membrane.
- 3** Welded Pillow made of PVC.
- 4** Male luer lock connector made of ABS with closed PP cap.
- 5** Expansion Chamber "Exp.26" made of rigid PVC.
- 6** Drip chamber made of Soft PVC with 270 micron polypropylene filter.
- 7** Two liters PVC discharge bag.

Big and small coloured clamps made of Polypropylene.

Female luer lock made of PVC.

Vented caps in Polyethylene and caps for female luer lock made of ABS.

Patient connectors, dialyzer connectors, pump connectors and chamber covers made of PVC.

(Tubing Lengths expressed in mm.)



NO LATEX



diaLine[®]

**A/V SET compatible
with COMBI
Gambro/Fresenius**

LK70605

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 assembling is made in our 100.000 class Clean Room (UNI EN ISO 14644). The biocompatibility of all the materials is tested in accordance with ISO 10993 standard. ALL OUR SETS ARE 100% AIR-TIGHTNESS TESTED.

Set features:

Length: 701 cm

Weight: 0,365 Kg

Blood Volume: 181 ml

Bar code: 8033254731859

Packaging:

Pouch made of 2 different materials: plastic film and medical – grade paper weight 60 gr/m², in accordance with EN868.

Labeling in compliance with UNI EN 1041 and UNI EN 980.

Box size: cm. 40 x 60 x 26 h.

Packaging Unit: 20 pcs. / box

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

Instruction for use in different languages in each box.

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, UNI EN ISO 11137.

Sterility guaranteed for 5 years. Not to be resterilized.

Product Shelf Life: 5 years from date of manufacture.

Conformity

Standard applicable to the product: EN ISO 9001, ISO 13485, ISO 10993, EN 1283, ISO 11135, ISO 11137, EN 20594, EN 980, EN 1041, EN 868, EN ISO 14644-1, ISO 2859, EN ISO 14971.

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Produced by:

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

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FABBRICAZIONI MEDICALI