# DEHP FREE NO LATEX

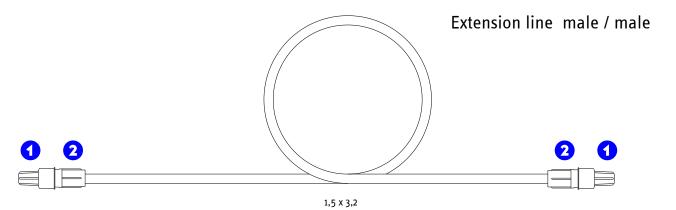








Code	FM code	Length mm
ML PDF900MM	LIB61	900
ML PDF1200MM	LIB64	1200
ML PDF1500MM	LIB62	1500
ML PDF3000MM	LIB63	3000



- 1 Vented cap made of PE.
- Male luer lock connector made of ABS.

**Tubing** is made of DEHP-FREE PVC 86 ShA. (Tubing Lengths expressed in mm.)

CE risk class: Ila

#### **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:**

 $\underline{\textbf{Blister}}$  made of 2 different materials: plastic film and

medical - grade paper

Box size: cm. 58 x 22 x 26,5 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

