

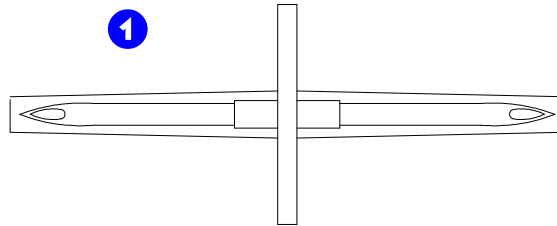
**DEHP FREE  
NO LATEX**

**DKS**<sup>®</sup>  
OVERSAN ACCESSORIES

**EffeEmme**<sup>®</sup>  
FABBRICAZIONI MEDICALI



**0179-0062  
FM code : LCP13  
Transfer spike**



**1** Double spike made of ABS and caps made of PE.

**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 (UNI EN ISO 14644). Each material is tested for biocompatibility according to ISO 10993 standard.

**Packaging:**

**Blister** made of 2 different materials: plastic film and medical – grade paper.

Labeling in compliance with UNI EN 1041.

**Box size:** cm. 60 x 31,5 x 28 h.

**Packaging Unit:** 500 pcs. / box (10 small boxes of 50 pcs. each).

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 ISO 11135, ISO 11137, EN 556. Sterility guaranteed for 5 years. Not to be resterilized.

**Product Shelf Life:** 5 years from date of manufacture.

**Conformity :**

Standard applicable to the product: ISO 13485, ISO 11135, ISO 11137, ISO 10993, ISO 11607, UNI EN 1041, ISO 14971, ISO80369-7.

**Produced by:**

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