

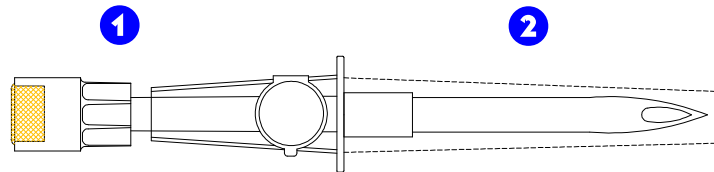
DEHP FREE  
NO LATEX

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

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



**AP2 0084**  
**FM code : LCP16**  
**Transfer spike**



- 1** Thin Latex-free Injection site made of ABS.
- 2** Two way female **Luer lock Spike** made of ABS with PE vented cap and 1,2 $\mu$  hydrophobic filter.

**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 and UNI EN 980.

**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 UNI EN ISO 11135, UNI EN ISO 11137, EN556. Sterility guaranteed for 5 years. Not to be resterilized.

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

**Compliance:**

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

**Produced by:**

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

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