

## 40 cm Pharmaceutical Preparation IV Set with Bag Adaptor Spike

### TECHNICAL DATASHEET

The Chemfort™ Bag spike firmly connects between a standard IV bag or semi rigid container and any gravity IV administration set. A safe drug transfer from the syringe into the IV bag or semi rigid container is installed through a closed connection with the Chemfort™ Syringe Adaptor/Syringe Adaptor Lock.

A “click” sound indicates a safe connection between two Chemfort™ components. A simple pinch on the SA wings will disconnect it from the Bag Adaptor SP. The self-sealing elastomers prevent drug leakage and droplet formation on the outer septa surfaces. The Chemfort™ portfolio has no known incompatibilities with hazardous drug solvents.

#### **Indications for Use:**

Preparation and administration of non-photosensitive antineoplastic chemotherapy drugs. Suitable for use with bottles, bags and ecoflacs. The device, suitably connected to the dedicated administration set, creates a closed circuit for the safe administration of the drug.

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#### Order Information

Article number / Reference	14071004
Transport box quantity	100 pcs

#### Product Characteristics

##### Product technical data

Spike type	Non-vented 2-way spike
Priming volume	3.4 ml
Total length	45 cm
Clamp type	Pinch clamp, red color
Distal end of the tubing	Male luer lock connection with flow-stop protection cap
Port connection disconnection	10
Shelf life	3 years
Sterilization	Ethylene Oxide

Tolerates disinfection with alcohol 70% and chlorhexidine in alcohol (5 mg/70% alcohol)

#### Material Specifications

















PVC DEHP-free. Non-pyrogenic. Free from latex, lead, cadmium, arsenic and hexavalent chromium. Meets standards and regulations with regards to the environment.

Component	Material
Protective cap on spike	Polyethylene
2-way Spike	Copolyester
Elastomer sealing	Polyisoprene
Soft tubing	PVC DEHP-free
Pinch clamp on tubing	Acetal
Male luer lock body	MABS
FlowStop protection cap	Polypropylene and PVDF mambrane

#### Regulation

CE 0051
UNI EN ISO 13485
ISO 10993-1

Symbols taken from ISO 15223-1:2021

 Consult instructions for use	 Medical device	 Single barrier system and sterilized using ethylene oxide	 Non-pyrogenic	 Do not re-sterilize	 Do not re-use	 Do not use if package is damaged	 Keep dry	 Keep away from sunlight	 Fragile, handle with care	
 LATEX	 DEHP	 CE 0051	 CH REP	confinis ch-rep ag Hauptstrasse 16 3186 Dudingn Switzerland		 SIDAM s.r.l. Via Statale Sud, 169 41037 San Giacomo Roncole, MIRANDOLA (MO) - ITALY Tel. +39 0535 25523	Simplivia Healthcare LTD. North Industrial Zone Kiryat Shmona, 1101801 Israel			