

11 cm Pharmaceutical Preparation IV Set with 0.2 µm Filter, Amber Tubing, Syringe Adaptor & Luer Lock Adaptor

TECHNICAL DATASHEET

The closed preparation set includes a Chemfort™ Syringe Adaptor component, which is connected to the Chemfort™ Bag Adaptor CP, which is firmly connected to a standard IV bag or semi-rigid container.

Its unique design presents a Chemfort™ Syringe Adaptor (SA) component that connects to the Bag Adaptor CP allowing a safe drug transfer through a closed connection between Chemfort™ devices. It incorporates an internal 16G needle that allows easy withdrawal of drugs, including viscous ones. The needle has a self-retracting mechanism that protects the operator from needle-stick injuries. During manipulation, a “click” sound indicates a safe and secure connection between two Chemfort™ components.

The self-sealing elastomers prevent drug leakage and droplet formation on the outer septa surfaces. A simple pinch on the SA component wings will disconnect the SA from the Bag Adaptor CP. The system is still closed after the disconnection.

Chemfort™ portfolio has no known incompatibilities with hazardous drug solvents.

Indications for Use:

Preparation and administration of 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

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|----------------------------|----------|
| Article number / Reference | 14081008 |
| Transport box quantity | 100 pcs |

Product Characteristics

Product technical data

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|-------------------------------|---|
| Total length | 20 cm |
| Priming volume | 3.3 ml |
| Clamp type | Pinch clamp, red color |
| Distal end of the tubing | Luer lock adaptor |
| Filter | In-line filter with 0.2 micron membrane |
| 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


















| Component | Material |
|---------------------------------|--|
| Soft tubing | Amber PVC DEHP-free |
| Pinch clamp on tubing | Acetal |
| 0.2 micron filter | Acrylic based polymer, PES (Polyethersulfone) and PTFE |
| Syringe Adaptor cap | Polyethylene |
| Syringe Adaptor body and clamps | Polyacetal |
| Elastomer housing | Copolyester |
| Elastomeric sealing | Polyisoprene |
| Spring | Stainless steel |
| Needle | Stainless steel |
| Hub | Copolyester |
| LL/F connector | PVC DEHP-free |
| Luer lock adaptor | Copolyester and polyisoprene |

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

Regulation

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|------------------|
| CE 0051 |
| UNI EN ISO 13485 |
| ISO 10993-1 |

Symbols taken from ISO 15223-1:2021

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|---|---|--|--|--|--|--|---|--|--|---|
|  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 |  |
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