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广东百合医疗科技股份有限公司
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Technical Data Sheet for Hemodialysis Catheter

Hemodialysis Catheters, produced by Guangdong Baihe Medical Technology Co., Ltd. conforms to Annex II of Council EC Directive 93/42/EEC on Medical Devices, as amended, and FDA 510K. Technical Data is as below:

Product code: FR-2613

Key contents of the kit:

Double Lumen TPU Hemodialysis Catheter 6.5Fr x 10cm with catheter clamp (size and priming volume indicated) and Luer lock for pediatric use with rotatable fixing wing, inner lumen 16/16Ga, Radiopaque, detectable on X-rays, markings on the length of the catheter, atraumatic catheter soft tip --- 1 piece

Raulerson syringe 5 ml --- 1 piece

Straight introducer needle 20G x 33+/-5 mm --- 1 piece

Nitinol Guidewire with dispenser 0.021" x 500mm with markings every 10 cm --- 1 piece

Dilator 7F x 10cm --- 1 piece

Injection needle 7# --- 1 piece

Curved needle with silk suture --- 1 piece

Heparin caps --- 2 pieces

Wound dressing --- 1 piece

Scalpel 11# --- 1 piece

Flow rate

Arterial line	Venous line
85ml/min	90ml/min

Packaging

Single units: Kit packed in blister with Tyvek paper.

	Number of pieces	Dimensions
Unit Box	10	350*215*165mm
Inner Carton	40	510*420*410mm
Shipping Carton	80	540*450*850mm

Sterilization

With ethylene oxide to a Sterility Assurance Level of at least 10^{-6}

Storage

Shelf life of 3 years.



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- The lot number and expiry date are printed on the label put on the blister pack.
 - Do not store at extreme temperature and humidity.

Precautions of use

Do not use if sterile packaging is damaged or opened.

For single use only.

Dispose of safely after single use to avoid risk of infection.

Quality tests

Structural tests

- Surface
- Corrosion resistance
- Force at break
- Force at break at soft tip
- Force at break of catheter
- Freedom of leakage
- Hubs
- Flowrate

Biological tests

ISO Maximization Sensitization Study

ISO AMES Mutagenicity Study of a Saline Extract

ISO 10993.11 Systemic Toxicity Study Extract

ISO 10993.4 IN VITRO Hemolysis Study Modified ASTM-EXTRACTUIN Method

ISO Test for IN VITRO Cytotoxicity

ISO Mouse Bone Marrow Micronucleus Study

Intracutaneous Reactivity Study In the Rabbit Conducted In according with the provision of the ISO10993.10

Genotoxicity: In Sperm Aberration Study in the mouse conducted in according with the provision of the ISO 10993.3(Extracts)

Chemical tests

- ETO residual