



## 贝恩医疗设备（广州）有限公司

地址：中国广州市经济技术开发区东区骏成路 10 号 邮编：510760  
Bain Medical Equipment (Guangzhou) Co., Ltd.  
Add: No. 10, Juncheng Road, Eastern Section, Guangzhou Economic &  
Technological Development District, Guangzhou, China 510760  
Tel: 86-20-82265249 Fax: 86-20-32067500  
Website: [www.bainmedical.com](http://www.bainmedical.com)

### DECLARATION OF CONFORMITY

Date: 20/12/2012

Manufacturer's Name: BAIN MEDICAL EQUIPMENT (GUANGZHOU) CO., LTD.  
Manufacturer's Address: NO.10 JUNCHENG ROAD, EASTERN AREA, ECONOMIC AND  
TECHNOLOGICAL DEVELOPMENT DISTRICT GUANGZHOU 510760 CHINA

Name of Device/: TUBING SETS FOR HEMODIALYSIS  
Range of Device DISPOSABLE AV FISTULA NEEDLE SETS  
Remark: Produced under "DORA" Trade Mark

Model/Type:	BAIN-BL-001	BAIN-BL-002	BAIN-BL-003
	BAIN-BL-001U	BAIN-BL-001W	BAIN-BL-001P
	BAIN-BL-001UP	BAIN-BL-001G	BAIN-BL-001UG
	BAIN-BL-002G	BAIN-BL-001OB	BAIN-BL-001UOB
	BAIN-BL-002OB	BAIN-BL-001UW	BAIN-BL-002W
	BAIN-AVF-001A	BAIN-AVF-001V	BAIN-AVF-0011A
	BAIN-AVF-0011V	BAIN-AVF-002A	BAIN-AVF-002V
	BAIN-AVF-0022A	BAIN-AVF-0022V	

Classification: Directive 93/42/EEC  
Classification no./ IIA  
Range of Device  
Reference of Notified Registration No.: HD 60035006 0001  
Body Certification: Report No.: 17013633 002  
Notify No.: 0197 to the EC Commission  
Notify Body: TÜV Rheinland LGA Products GmbH

European Representative: **MT Promedt Consulting GmbH**  
Altenhofstrasse 80 D-66386 St. Ingbert, Germany  
Tel: +49 (0) 6894 581020 Fax: +49 (0) 6894 581021

I, the undersigned, hereby declare that the medical device(s) specified above conforms with the Essential Requirements listed in Annex II, Article 3 of EC Directive 93/42/EEC, and the conformity assessment route requirements as in Annex II, Article 5.

*Bain Medical Equipment (Guangzhou) Co., Ltd.*

.....  
*Ms. Mu Fangzhen*  
*Manager of Quality Control*



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Name of Device/: DISPOSABLE AV FISTULA NEEDLE SETS  
Range of Device

Remark: Produced under "FLEXISET" Trade Mark

Model/Type: SIM-AVF1525-A, SIM-AVF1525-V, SIM-AVF1625-A, SIM-AVF1625-V  
SIM-AVF1725-A, SIM-AVF1725-V, SIM-AVF1525-AR, SIM-AVF1525-VR,  
SIM-AVF1625-AR, SIM-AVF1625-VR, SIM-AVF1725-AR, SIM-AVF1725-VR

Classification: Directive 93/42/EEC  
Classification no.: DISPOSABLE AV FISTULA NEEDLE SETS IIA  
Range of Device

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## Disposable AV Fistula Needle sets

Manufacturer has been granted certificate of ISO 13485

### 1. Material

The major components of this product are made from medical-grade PVC, PP, fire-retardant PE and other medical-grade macromolecule materials and innocuous stainless steel. And this product is free of latex.

### 2. Product configuration and Feature

AVF fistula needle set can be inserted to patient's vein, and then connected to Hemodialysis bloodline tubing set. The material is soft, transparent, smooth and non-kink. The wing of the needle set is proper rigidity suitable for use. The on-off clamp is simple and convenient for use. The wing for 15G is Blue, 16G is Green and 17G is Red. The tip of the cannula is sharp to reduce the pain for the patient. The back-eye is slender close to the cannula tip. It is designed with slippery prevention for smooth puncture.

### 3. Technical Performance

The products is fully sterilized by Ethylene Oxide gas, sterility and non-pyrogenicity, non-toxicity; non-haemolytic reaction. Its performance of chemistry and physics meets the requirements of ISO 1135.

### 4. Indication for use

This product is intended to be used as vein puncture for the hemodialysis treatment.

### 5. Usage method

- 1) Take out the needle set from the pouch.
- 2) Disinfect the skin where is intended to puncture.
- 3) Screw out the cap for a female luer lock.
- 4) Pick out the cap for cannula.
- 5) Hold the wing, and then puncture the vein.
- 6) Clamp the tubing when the blood goes into the tubing, allow all of the air out flow.
- 7) Fix the cannula on the puncture part by the medical adhesive tape.
- 8) Connect with the bloodline tubing set.

### 6. Transportation and storage

Please avoid crash and exposure to rain, snow or direct sunlight during transportation. Store this product in 0°C~40°C, well-ventilated indoor place with relative humidity no more than 80%, without corrosive gases. DO not store this product in warehouse with chemicals and moist articles.

### 7. Precautions in use

- 1) Using this device should be supervised by a physician. Use aseptic technique throughout priming and treatment. The validity period of sterilization is three years. The expiration date should be checked prior to use. To prevent contamination or infection, DO not use any expired product.
- 2) This product has been sterilized by Ethylene Oxide gas. Do not use the product if the package is damaged.
- 3) Tear along the open line and take tubing out of its package. Proper force should be applied to avoid smash.
- 4) After unpacking, please ensure aseptic operation on related parts of tubing and correctly install this product according to the type of dialysis equipment.
- 5) The safety of the connection to bloodline tubing set should be guaranteed. Check from time to time to ensure that all connectors are tight. If the joints of this product cannot be closely tightened or there is occurrence of tiny air-bubbles or slight leakage, treatment or readjustment should be performed by physician. In case no improvement is made,










replace with another new one. Any abnormal conditions should be properly treated under the direction of physician.

- 6) If tubing cannot be properly connected, or there is any fluid leakage or presence of air bubbles, treatment or adjustment should be performed by a physician. If no correction can be made, replace with a new tubing set. Any abnormal condition should be properly treated under the direction of a qualified physician.
- 7) This product is for single use only and reuse is strictly prohibited. Reprocessing of this product may lead to adverse patient reactions and/or device failure. It should be discarded according to laws and regulations relevant to disposal of infectious medical waste so as to prevent infection.
- 8) Attention should be paid when this product is used for pregnant women, breastfeeding mothers, infants, and children since this contains phthalates.

### 8. After sales service

Please keep the original packing for any investigation on product quality.

### 9. Symbol

	Single use only
	Manufacture date
	Use by
	Caution
	Sterilized by ethylene oxide gas
	Lot Number
	Reference Number
	Do not use if package is damaged
	Product containing DEHP



Keep this Instruction for Use UNTIL all of the products in this carton have been used.

#### TÜRKİYE DİSTRİBÜTÖRÜ:

Sesa Elektronik A.Ş.  
Dr Ali Nihat Tarlan Cd Kartal Sk No:15 34744  
İçerenköy – Bostancı / İSTANBUL  
www.sesa.com.tr

**EC REP** <EU Representative>

**MT Promedt Consulting GmbH**

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