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

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./ Range of Device: IIA
Reference of Notified Body Certification: Registration No.: HD 60035006 0001
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.

Digitally signed by Talpiș Andrei
Date: 2019.02.07 19:41:03 EET
Reason: MoldSign Signature
Location: Moldova

Ms. Mu Fangzhen
Manager of Quality Control

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
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Tel: 86-20-82265249 Fax: 86-20-32067500
Website: 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/: Range of Device	DISPOSABLE AV FISTULA NEEDLE SETS
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.: Range of Device	DISPOSABLE AV FISTULA NEEDLE SETS IIA
Reference of Notified Body Certification:	Registration No.: HD 60035006 0001 Report No.: 17013633 002
Notify No.:	0197 to the EC Commission
Notify Body:	TÜV Rheinland LGA Products GmbH

European Representative: **MT Promedt Consulting GmbH**
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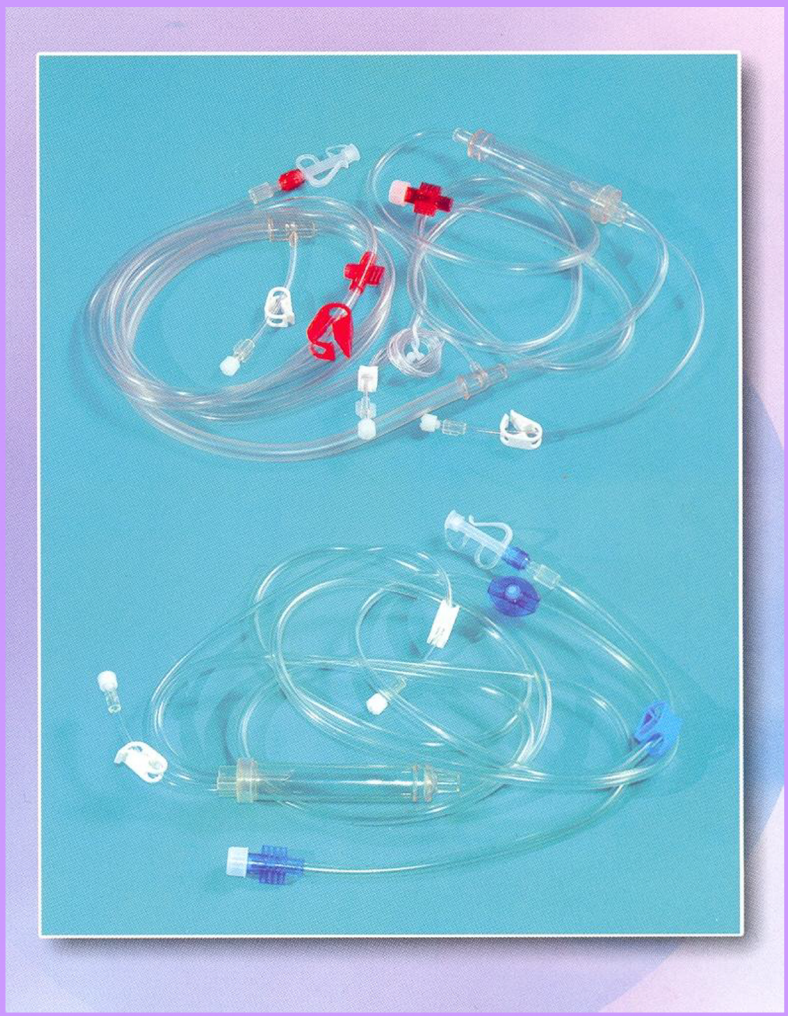
Bain Medical Equipment (Guangzhou) Co., Ltd.

……

Ms. Mu Fangzhen
Manager of Quality Control

DORA

DISPOSABLE ARTERIO VENOUS BLOODLINE SET



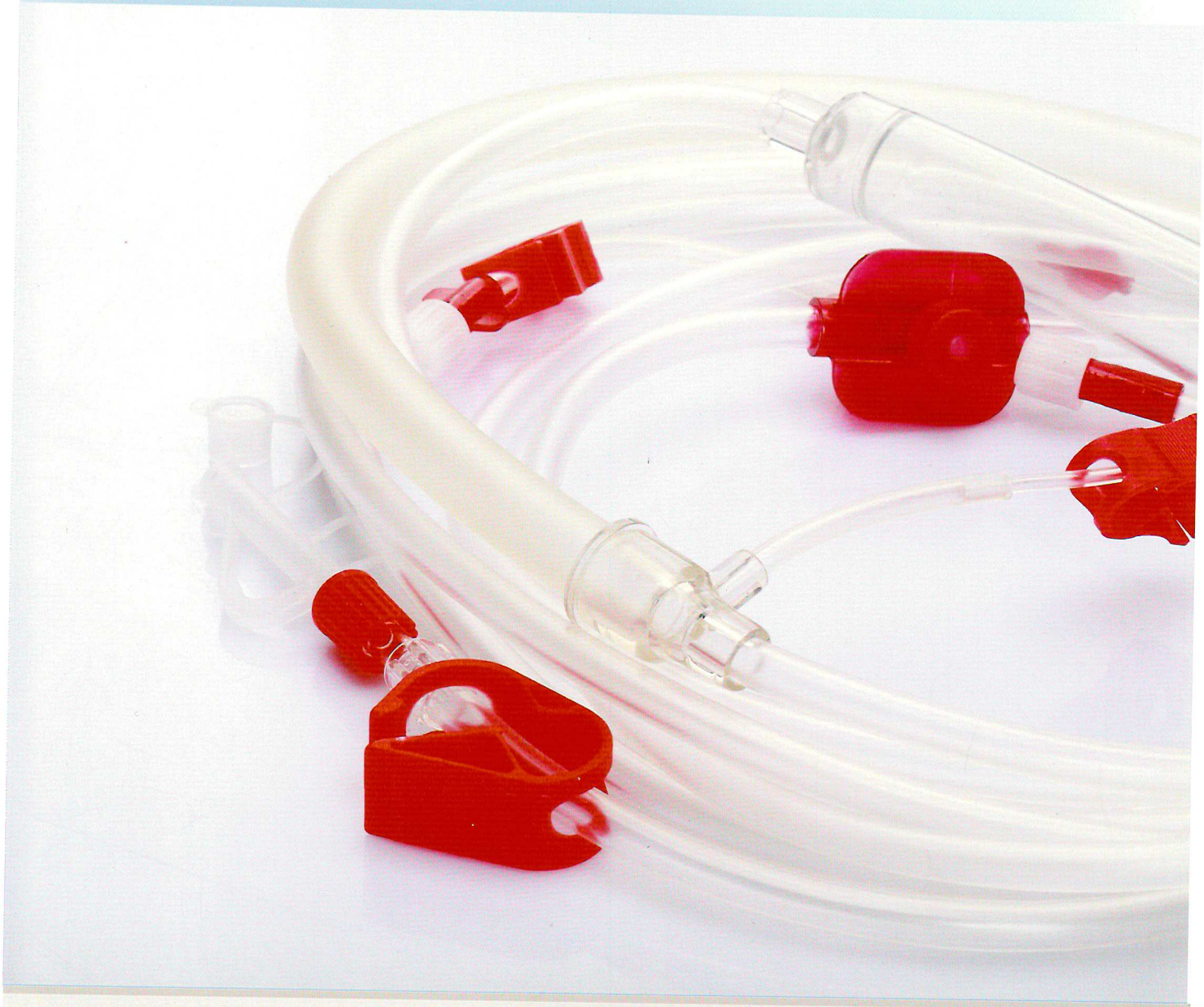
CE 0197

CODE	MACHINE	POMP SEGMENT IN/OUT DIAMETER	RESIDUAL VOLUME	PACKAGING
BAIN-BL-001	UNIVERSAL	6,3 mm 9,80 mm	152 ml	24 SET ARTERIAL & VENOUS/CARTOON
BAIN-BL-002	UNIVERSAL	8.0 mm 12.0 mm	159 ml	
BAIN-BL-001W	UNIVERSAL	6,3 mm 9,80 mm	152 ml	
BAIN-BL-002W	UNIVERSAL	8.0 mm 12.0 mm	159 ml	
BAIN-BL-001G	UNIVERSAL	6,3 mm 9,80 mm	152 ml	
BAIN-BL-001U	ALTIN	6,3 mm 9,80 mm	152 ml	
BAIN-BL-007	UNIVERSAL	8.1 mm12.2 mm	170 ml	
BAIN-BL-008	UNIVERSAL	8.1 mm 12.2 mm	136 ml	

TURKEY DISTRIBUTOR:
SESA ELEKTRONİK SAN. VE TİC. A.Ş.
Dr. Ali Nihat Tarlan Cd. Kartal Sk. No:15,
34752 İçerenköy Ataşehir – İstanbul
Tel +90 216 573 38 10 | +90 216 573 34 59
BAIN MEDICAL EQUIPMENT COMPANY

DORA®

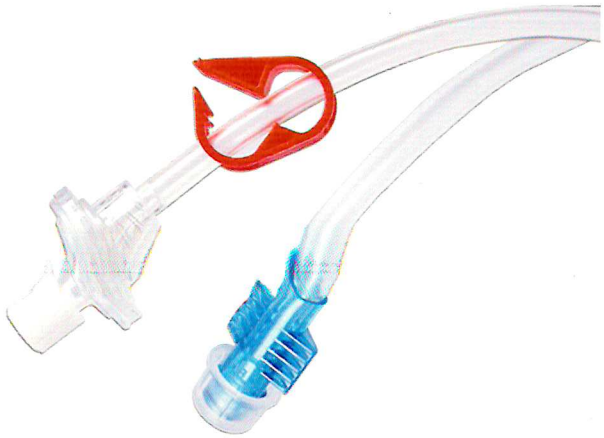
TUBING SETS FOR HEMODIALYSIS



BAIN MEDICAL EQUIPMENT(GUANGZHOU)CO.,LTD.

Add.:No.10 Juncheng Road Eastern Area,GETDD,Guangzhou,510760 China
Tel:+86-(0)20-66856868 Fax:+86-(0)20-32067500
E-mail:sales@baingz.com www.bainmedical.com

DORA®



MODEL	APPLICABLE MACHINE	STERILIZATION WAY
BAIN-BL-001	FMC 2008-4008	EO/GAMMA
BAIN-BL-002	FMC 2008-4008	EO/GAMMA
BAIN-BL-003	FMC 2008-4008	EO/GAMMA
BAIN-BL-004	FMC 2008-4008	EO/GAMMA
BAIN-BL-005	GAMBRO AK10/100/200/ 200 ULTRA	EO/GAMMA
BAIN-BL-006	GAMBRO AK100/200	EO/GAMMA
BAIN-BL-007	GAMBRO AK100/200	EO/GAMMA
BAIN-BL-008	BRAUN DIALOG	EO/GAMMA
BAIN-BL-009	BRAUN DIALOG	EO/GAMMA
BAIN-BL-010	FRES/GAMB/HOSP	EO/GAMMA
BAIN-BL-011	FRES/GAMB/HOSP/ BELLCO FORMULA 2000	EO/GAMMA
BAIN-BL-012	GAMBRO/FRESENIUS	EO/GAMMA
BAIN-BL-013	HOSPAL INTEGRA/ INTEGRALPHA	EO/GAMMA
BAIN-BL-014	NIKKISO DBB-03/05/06/07	EO/GAMMA
BAIN-BL-015	NIKKISO DBB-03/05/06/07	EO/GAMMA
BAIN-BL-016	NIKKISO DBB-03/05/06/07	EO/GAMMA
BAIN-BL-017	NIKKISO DBB-03/05/06/07	EO/GAMMA
BAIN-BL-018	NIKKISO DBB-03/05/07	EO/GAMMA
BAIN-BL-019	NIPRO	EO/GAMMA
BAIN-BL-020	TORAY	EO/GAMMA

★ DEHP FREE Bloodlines are available on demands.

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：5 0760
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Tel: 86-20-82265249 Fax: 86-20-32067500
Website: www.bainmedical.com

DECLARATION OF CONFORMITY

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

Date: 11/06/2015

Name of Device/: TUBING SETS FOR HEMODIALYSIS
Range of Device
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

Classification: Directive 93/42/EEC
Classification no./ Range of Device: TUBING SETS FOR HEMODIALYSIS IIA
Reference of Notified Body Certification: Registration No.: HD 60101337 0001
Report No.: 17038049 003
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.
For and on behalf of
BAIN MEDICAL EQUIPMENT (GUANGZHOU) CO.,LTD.
贝恩医疗设备（广州）有限公司

.....
Authorized Signature(s)

Mr. Li Zhongming
Manager of Quality Control

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

TÜVRheinland®

Registration No.: HD 60101337 0001

Report No.: 17038049 003

Manufacturer:

Bain Medical Equipment
(Guangzhou) Co., Ltd.
No. 10, Juncheng Road,
Eastern Area, Economic and
Technological Development District
Guangzhou 510760
China

For and on behalf of
BAIN MEDICAL EQUIPMENT (GUANGZHOU) CO., LTD.
贝恩医疗设备（广州）有限公司

Authorized Signature(s)

Products:

Medical Devices

(see attachment for products and additional site included)

Replaces Approval, Registration No.: HD 60096708 0001

Expiry Date: 2019-05-14

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2015-06-10

Date: 2015-06-10

Notified Body

TÜV Rheinland LGA Products GmbH

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate Registration No.: HD 60101337 0001
Report No.: 17038049 003

For and on behalf of
BAIN MEDICAL EQUIPMENT (GUANGZHOU) CO.,LTD.
贝恩医疗设备（广州）有限公司

Authorized Signature(s)

Manufacturer:

Bain Medical Equipment
(Guangzhou) Co., Ltd.
No. 10, Juncheng Road,
Eastern Area, Economic and
Technological Development District
Guangzhou 510760
China

Products:

Disposable A.V. Fistula Needle Sets, Tubing Sets for Hemodialysis, Tubing Sets for Blood Purification, Hemodialyzers, Heamodialysis procedure packs with syringe; Aspects of manufacture concerned with securing and maintaining sterile conditions: Drain Bags, heamodialysis procedure packs without syringe

Site included:

No. 10, Banhe Road, Economic and Technological Development District, Guangzhou, 510535, China

Manufacture of Hemodialyzers

Date: 2015-06-10

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Notified Body

X. Ren

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
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Tel: 86-20-82265249 Fax: 86-20-32067500
Website: 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./ Range of Device: IIA
Reference of Notified Body Certification: Registration No.: HD 60035006 0001
Report No.: 17013633 002
Notify No.: 0197 to the EC Commission
Notify Body: TÜV Rheinland LGA Products GmbH

European Representative: **MT Promedt Consulting GmbH**
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Tel: +49 (0) 6894 581020 Fax: +49 (0) 6894 581021

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Bain Medical Equipment (Guangzhou) Co., Ltd.

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Ms. Mu Fangzhen
Manager of Quality Control

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Name of Device/: Range of Device	DISPOSABLE AV FISTULA NEEDLE SETS
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.: Range of Device	DISPOSABLE AV FISTULA NEEDLE SETS IIA
Reference of Notified Body Certification:	Registration No.: HD 60035006 0001 Report No.: 17013633 002
Notify No.:	0197 to the EC Commission
Notify Body:	TÜV Rheinland LGA Products GmbH

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Bain Medical Equipment (Guangzhou) Co., Ltd.

……

Ms. Mu Fangzhen
Manager of Quality Control

DORA®

CE 0197

Tubing Sets for Hemodialysis

Instruction for Use

Manufacturer has been granted certificate of ISO13485

1.Material

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

2.Product configuration and Feature

The tubing set consists of a red Arterial line and a blue Venous line, The tubing is soft, transparent, smooth and non-kink, which ensure the good liquidity of the tubing. The filter in the venous chamber can prevent the blood clot going into patient's vein.

3.Technical Performance

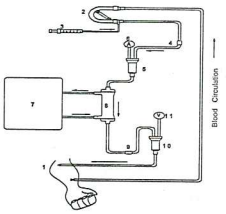
The products is fully sterilized by Ethylene Oxide gas, sterility and non-pyrogenicity.

4.Indication for use

This product is intended to connect with the dialyzer to the patient in dialysis treatment.It can be used with all the dialysis machine.

5.Usage method

1) Pick out the tubing from the pouch, the Arterial and Venous connectors should be connected correctly with the dialyzer's arterial and venous ports respectively.
2) Priming using physiological saline, removing all of the air from the tubing and the dialyzer.
3) Before the 5.2 step finished, use heparin saline prime the tubing and the dailyzer, which ensure the tubing is full of the heparin saline, then stop pumping, clamp all of the tubings.
4) Recheck all the connectors, make sure all of the connectors are tight.
5) Start treatment referring to the dialyzer Instruction for Use.
6) The typical bloodline circuit diagram



1. Patient
2. Blood pump
3. Heparinization
4. Access port of the arterial line
5. Air capture chamber of the arterial line
6. Arterial pressure
7. Dialysate
8. Dialyser
9. Access port of the venous line
10. Air capture of the venous line.
11. Venous pressure

6.Transportation and storage

Please avoid crash or exposure to rain, snow or direct sunlight during transportation. Store it in 0℃~40℃, well-ventilat ed indoor place with relative humidity no more than 80%, without corrosive gas. DO not store it in warehouse with chemicals and moist articles.

7.Precautions in use

1) This product should be used under medical supervision.
Use aseptic technique throughout connection,priming and treatment. The validity period is three years after the sterilization day.Please checked the expiration date priorto use, to prevent contamination or infection, DO not use any expired product.
2) Do not use the product if the pouch is damaged.
3) Open the pouch and pick out the tubing set caref ully.
4) The safety of the connection to dialyzers should be guaranteed.
Do not use this product if the dialyzer connector can not fit for the dialyzer. Check from time to time to ensure that all of connectors are tight to prevent blood leakage or the air bubbles and avoid air embolism caused by entry of air into the patient. Make sure the tubing set is properly installed to the dialysis machine to prevent kinking during treatment.
5) If the tubing set can not be properly connected, or there is any fluid leakage or presence of air bubbles, treatment or readjustment should be performed by physician. In case no improvement is made, replace with another new tubing set. Any abnormal condition should be properly treated under the direction of physician.
6) 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.
7) The transducer protector of this product is welded by high frequency bonding technology, if it is wetted by saline or blood during dialysis, it should be clamped the tubing which connects with the transducer protector, and then replace with another new transducer protector.Make sure that a transducer protector must be installed on each pressure monitoring line prior to patient use.
8) Attention should be paid when this product is used for pregnant women,breastfeeding mothers,infants and children since this contains phthalates.
9) All of the disinfectant used for this product have no special contraindications.
10) To ensure the normal use of the air-capture chamber, its level marking should below 1cm of the upper limit.

8.After sales service

Please keep the original packing for any investigation on product quality

9.Symbol

	Single use only	STERILE EO	Sterilized using Ethylene Oxide
	Manufacture date	LOT	Lot Number
	Use by	REF	Catalogue number
	Caution		Do not use if package is damaged
PHT DEHP	Contain DEHP		Pump segment diameter

10.parameter

Positive pressure (mmHg)	Negative pressure (mmHg)	Blood pathway volume(A±10%)	blood flowrate limitations
500	-500	A= 151 ml	500ml/min

EC REP <EU Representative>
MT Promedt Consulting GmbH
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<Manufacturer>
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Tel: +86-20-82256562 Fax:+86-20-32067500
E-mail: sales@baingz.com

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

Keep this Instruction for use after all of the products in this carton are used up.