EC Certificate

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

Registration No.: HD 60097258 0001

Report No.: 17042992 001

Manufacturer:
Vital Healthcare
Sdn. Bhd.
Lot 3, Jalan Sultan Mohamed 3
Bandar Sultan Sulaiman
42000 Pelabuhan Klang, Selangor Darul Ehsan
Malaysia

Products:
Tubing Sets for Hemodialysis, Disposable AV Fistula Needle Sets, Disposable AV Fistula Needle Sets (Dull Needle series with Scab Remover), Disposable AV Fistula Needle Sets (Safety Needle series), Hollow Fiber Dialyzer

Expiry Date: 2019-12-25

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: 2015-03-04

Date: 2015-03-04

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

S. Liu

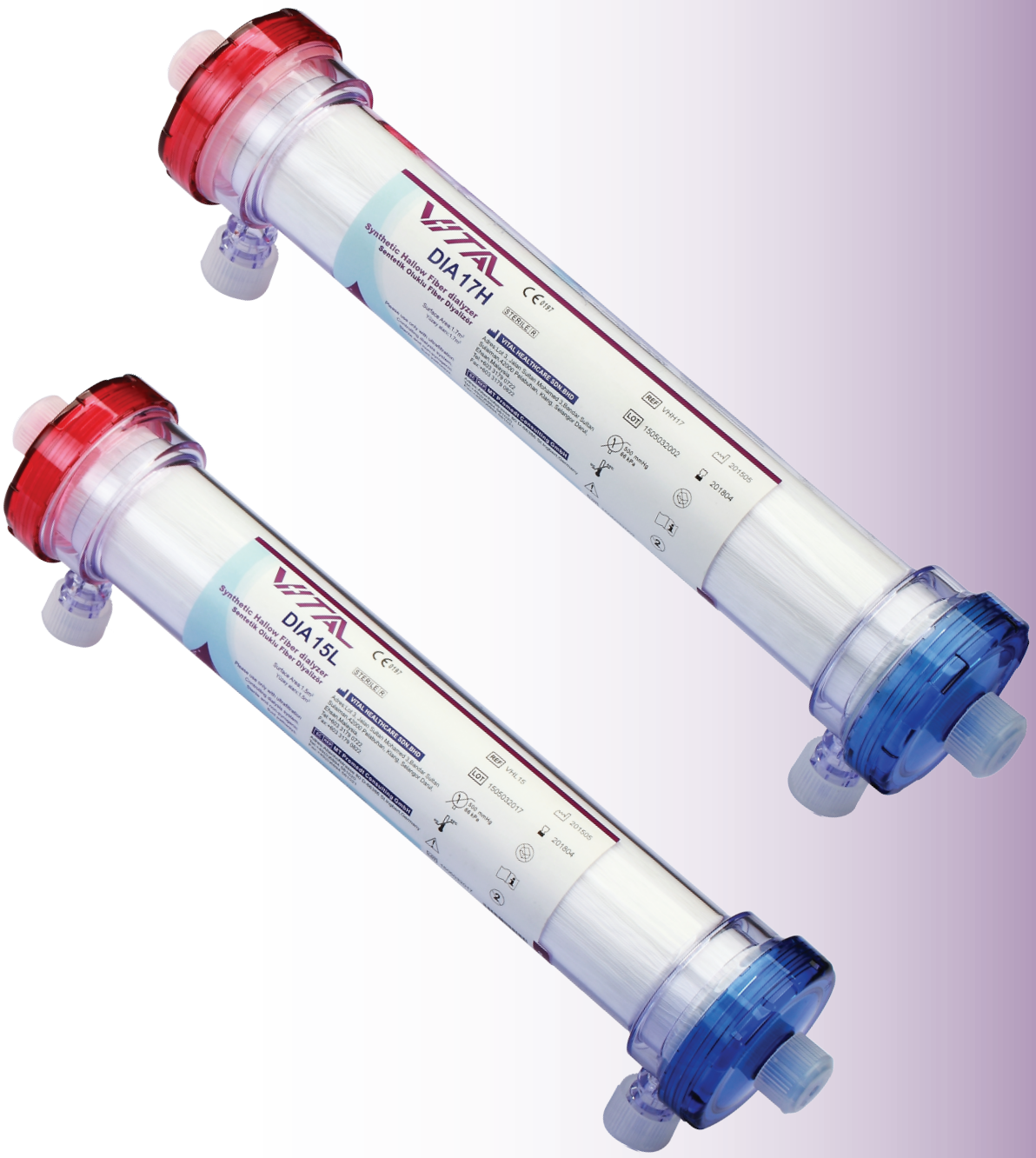
TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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

Digitally signed by Talpiş Andrei
Date: 2019.02.07 19:30:56 EET
Reason: MoldSign Signature
Location: Moldova

HEMODIALYZER

New Performances for **Vital** Parameters



CE
0197

Hemodialyzer

Specifications & Performance

Low Flux

Model		DIA 13L			DIA 15L			DIA 17L			DIA 19L			DIA 21L		
QB(ml/min)		200	300	400	200	300	400	200	300	400	200	300	400	200	300	400
Clearance (ml/min)	Urea	188	253	277	191	260	287	194	267	294	197	274	301	199	279	306
	Creatinine	179	221	254	183	230	265	187	237	273	191	244	281	194	250	288
	Phosphate	151	177	198	158	197	219	165	199	238	169	204	246	173	209	260
	Vit.B_{12}	98	109	118	105	113	124	109	127	139	113	134	147	116	139	152
	KoA(Urea)	861			961			1083			1239			1382		
UFR(ml/hr.mmHg)		16			18			19			21			23		
Wall thickness(μm)		35														

Test condition: QD=500ml/min, QF=0ml/min, temperature 37±1℃

High Flux

Model		DIA 13H			DIA 15H			DIA 17H			DIA 19H			DIA 21H		
QB(ml/min)		200	300	400	200	300	400	200	300	400	200	300	400	200	300	400
Clearance (ml/min)	Urea	191	258	308	193	265	318	195	273	328	196	278	338	197	283	348
	Creatinine	179	233	278	183	248	293	188	258	303	193	268	315	197	278	328
	Phosphate	174	218	258	179	233	263	183	248	283	188	260	295	193	265	308
	Vit.B_{12}	145	168	178	153	173	188	163	193	198	173	206	210	178	218	221
	Inulin	113	118	128	116	128	140	123	138	153	139	158	165	164	178	181
	KoA(Urea)	930			1045			1214			1351			1527		
UFR(ml/hr.mmHg)		61			70			77			83			88		
Sieving Coefficients (S.C.)	Inulin	0.9±10%														
	β_2-microglobulin	0.8														
	Myoglobin	0.55														
	Albumin	< 0.01														
Wall thickness(μm)		30														

Model	DIA 13H/L	DIA 15H/L	DIA 17H/L	DIA 19H/L	DIA 21H/L
Priming Volume	78ml	86ml	100ml	108ml	115ml
Membrane	Polyethersulfone				
Potting material	Polyurethane				
Housing and caps material	Polycarbonate				
Sterilization	Gamma Ray				
Internal diameter(μm)	200				
Max TMP(mmHg)	500				

Test condition:UFR:with anticoagulation bovine plasma,Hct 32%,proten 60±5g/L,temperature 37±1℃,QB=300ml/min,TMP=50mmHg
S.C.:with anticoagulation bovine plasma,protein 60±5g/L,temperature 37±1℃,QB=200ml/min,QF=30ml/min

VITAL HEALTHCARE SDN.BHD.
Add.:Lot 3, Jalan Sultan Mohamed 3,Bandar Sultan Sulaiman, 42000 Pelabuhan,Klang, Selangor Darul, Ehsan,Malaysia.Tel:+603 3179 0722 Fax:+603 3179 0822

Distributor : Proses Medikal Analitik Sistemler Paz. San. ve Tic. A.S.
Adres :Cetin Emec Bulvarı Lizbon Caddesi No:13/1-2-3-4-A 06460 Asagı Ovecler / Ankara - Turkey Tel :+90 312 472 1555 Fax :+90 312 472 1556

Rev: 2015.05.05 - V.01

EC Certificate

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Expiry Date: 2019-12-25

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: 2015-03-04

Date: 2015-03-04

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

S. Liu

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.

EC Declaration of Conformity

Manufacturer:
VITAL HEALTHCARE SDN.BHD.
Address: Lot 3, Jalan Sultan Mohamed 3,
Bandar Sultan Sulaiman, 42000 Pelabuhan Klang,
Selangor Darul Ehsan, Malaysia

EU Representative:
MT Promedt Consulting GmbH
Address: Altenhofstrasse 80 D-66386 St.
Ingbert, Germany .
Phone:++49-6894-581020
Fax:++49-6894-581021
DIMDI No.: DE/0000040838

We, the manufacturer, herewith declare that the products

Hollow Fiber Dialyzer

*(*including system components and accessories*)*

UMDNS-Code: 11-234 ; GMDN-Code:35004

Model codes: DIA13H, DIA15H, DIA17H, DIA19H, DIA21H

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIb according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.:HD 600972580001
Issue date: 2015.03.04
Expiry date: 2019.12.25

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: VITAL HEALTHCARE SDN.BHD.

Address: Lot 3, Jalan Sultan Mohamed 3, Bandar Sultan Sulaiman,
42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia

GUANGZHOU 2015-03-19

Place , date

Mu Fangzhen, Management Representative

Legally binding signature, Function

Hollow Fiber Dialyzer
(H Series)
Instruction for Use

CE 0197

Please read the Instruction for Use carefully before using the product.

Indications: VITAL Dialyzer can be used for the hemodialysis treatment of acute and chronic renal failure.

Contraindications: No absolute contraindication for hemodialysis treatment. Strict monitoring shall be achieved for the patients who have tendencies of blood bleeding or clotting during the treatment. In case of any complication that would affect the stable condition, the treatment shall be terminated.

Warning:

- The dialysate and the blood should flow in counter-current.
- The maximum flow rate of dialysate is 800 mL/min.
- Do not use on non-degas dialysis fluid delivery systems.
- During the treatment, the transmembrane pressure shall not exceed 500 mmHg.
- The blood flow rate shall not be less than 150 mL/min, but not more than 500 mL/min.
- The preparation for hemodialysis and treatment should be carried out under aseptic operation to avoid infection.
- VITAL Dialyzer shall be used under certain medical supervision. To avoid bacterial and pyrogenic contamination, it is suggested to use together with hemodialysis machine and dialysate which are in accordance with the international standards, and most importantly, with the water, concentrated solution and dialysate which are in accordance with the international standards.
- This dialyzer is sterile and nonpyrogenic, sterilized by Gamma ray,which shall be checked before use. To avoid infection, do not use the expired product.Do not use the product if the package is damaged.
- This dialyzer is for single use 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.
- If abnormal conditions arise during the dialysis, such as bubbles ,foreign body ,blood leak, clotting, or hemolysis, proper measures shall be taken according to doctor's advice.
- Color identification:

  Arterial: Red

  Venous: Blue

Instructions for Installation

- Take out the dialyzer from the pouch, and check whether the dialyzer and its components are in good condition.
- Set up the dialyzer vertically to the holder, the red (arterial) port is located downwards.
- Make sure the dialyzer stays firmly in the holder.

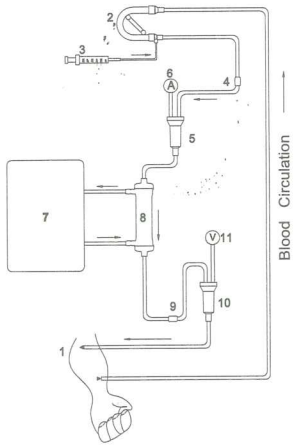
Instructions for Use

1. **Priming**
   - Prepare no less than 500ml normal saline and add appropriate amount of heparin if needed under the doctor's advice.
   - Place the arterial line and the venous line onto the dialysis machine according to the instructions for use of the blood line tubing set.
   - Connect the arterial line,the venous line and the dialyzer.
   - Control the flow rate of blood pump within 80~100ml/min,use normal saline to totally remove air from blood line and blood side of the dialyzer.The direction of normal saline flow is arterial line→dialyzer→venous line,and counter-current flow is forbidden.
   - Turn the flow rate up to 200~300ml/min,connect the dialysate and the dialyzer,and remove air from the dialysate side.

   Note: The dialyzer should be replaced if there is bubbles inside.
2. **Heparinization**
   - Carry out the heparinization process under the doctor's advice.
3. **Termination of Treatment**
   - Prepare 500 mL normal saline and turn off the blood pump.
   - Withdraw the arterial line from the patient and connect it to the normal saline then set the blood flow rate at 100 mL/min, meanwhile prevent air from the blood line. Intermittently clamp the venous line to return the blood to the patient as much as possible.
   - Turn off the blood pump and disconnect the patient's venous line.

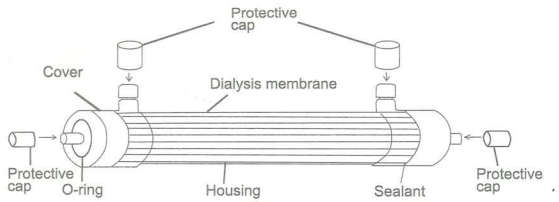
   Note: Do not turn off the air monitor system before blood returns completely to prevent the air flowing into the patient from the blood line.

A typical connection diagram



1.Patient
2. Blood pump
3. Heparinization
4. Arterial line sampling port
5. Arterial air capture
6. Arterial pressure
7. Dialysate
8. Dialyzer
9. Venous line sampling port
10. Venous air capture
11. Venous pressure

	Single use only		Date of manufacture
	Temperature limited	LOT	Lot Number
STERILE R	Sterilized using irradiation		Caution
	Do not use if package is damaged		Use-by date
EC REP	Authorised Representative in European Community		Manufacturer



Main Structure:

Component	Housing	Dialysis membrane	Cover	O-ring	Sealant	Protective cap
Material	Polycarbonate	PES membrane	Polycarbonate	Silicone Resin	Polyurethane	Polypropylene

Product Performance: This dialyzer has reliable performance, which can be used for hemodialysis. The basic parameters of product performance and the laboratory data of this series will be provided as follows for reference.

Note: The laboratory data of this dialyzer was measured according to the standards ISO 8637.

These data represent typical in vitro performance.actial in vivo perpormance will differ due to the patient's blood composition and clinical settings.

Model	**DIA 13H**			**DIA 15H**			**DIA 17H**			**DIA 19H**			**DIA 21H**		
Product ref.	**VHH13**			**VHH15**			**VHH17**			**VHH19**			**VHH21**		
Test Conditions: Q_D = 500mL/min, temperature: 37℃±1℃, Q_F =0 mL/ min															
Clearance /Q_B(mL/min)	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400
Urea (mL/min)	191	258	308	193	265	318	195	273	328	196	278	338	197	283	348
Creatinine (mL/min)	179	233	278	183	248	293	188	258	303	193	268	315	197	278	328
Phosphate (mL/min)	174	218	258	179	233	263	183	248	283	188	260	295	193	265	308
Vitamin B_{12} (mL/min)	143	168	178	153	173	188	163	193	198	173	206	210	178	218	221
Inulin (mL/min)	113	118	128	116	128	140	123	138	153	139	158	165	164	178	181
KOA(Urea)	930			1045			1214			1351			1527		
Pressure drop of blood compartment (mmHg)	<75	<105	<110	<60	<95	<100	<50	<85	<90	<45	<75	<80	<45	<70	<70
Pressure drop of dialysate compartment (mmHg) Q_D =500mL/min	<45			<40			<40			<40			<40		
Ultrafiltration Coefficient (mL/hr/ mmHg) Q_B=300mL/min, TMP=50mmHg	61			70			77			83			88		
Priming volume (mL)	78			86			100			108			115		
Effective membrane area (㎡).	1.3			1.5			1.7			1.9			2.1		
Sieving coefficients (S.C.) Q_B=200mL/min Q_F=30mL/min	Inulin：0.9±10% β_2- microglobulin：≥0.8 Myoglobin：≥0.55 Albumin：≤0.01														

Special Storage Conditions and Methods: Please avoid crash and exposure to rain, snow, and direct sunlight during transportation. Please store it in a well-ventilated indoor place with storage temperature of 0℃-40℃, with relative humidity no more than 80% and without corrosive gas. DO NOT store it in a warehouse together with chemicals and humid articles.

Shelf life: 3 years after the sterilization date.

After-sale service: if any product inquire is needed, due to manufacturing quality problem, please keep the primary package of the product for product tracing.

EC REP <EU Representative>
MT Promedt Consulting GmbH
Altenhofstrasse 80 D-66386 St. Ingbert, Germany
Tel:+49(0)6894581020 Fax:+49(0)6894581021

<Manufacturer>
VITAL HEALTHCARE SDN.BHD
Lot 3, Jalan Sultan Mohamed 3, Bandar Sultan Sulaiman, 42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia.
Tel:+603 3179 0722 Fax:+603 3179 0822

Distributor :**Proses Medikal Analitik Sistemler Pazarlama Sanayi ve Ticaret A.S.**
Adres :Cetin Emec Bulvarı 1065. Cadde No:12/1-1-3-4-A 06460 Asagı Ovecler/Ankara - Turkey
Tel : 0312 472 15 55 Fax : 0312 472 15 56

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

VH-AW0304G Rev 0 of 2015.7.23

Hollow Fiber Dialyzer
(L Series)
Instruction for Use

CE 0197

Please read the Instruction for Use carefully before using the product.

Indications: VITAL Dialyzer can be used for the hemodialysis treatment of acute and chronic renal failure.

Contraindications: No absolute contraindication for hemodialysis treatment. Strict monitoring shall be achieved for the patients who have tendencies of blood bleeding or clotting during the treatment. In case of any complication that would affect the stable condition, the treatment shall be terminated.

Warning:

- The dialysate and the blood should flow in counter-current.
- The maximum flow rate of dialysate is 800 mL/min.
- Do not use on non-degas dialysis fluid delivery systems.
- During the treatment, the transmembrane pressure shall not exceed 500 mmHg.
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- The preparation for hemodialysis and treatment should be carried out under aseptic operation to avoid infection.
- VITAL Dialyzer shall be used under certain medical supervision. To avoid bacterial and pyrogenic contamination, it is suggested to use together with hemodialysis machine and dialysate which are in accordance with the international standards, and most importantly, with the water, concentrated solution and dialysate which are in accordance with the international standards.
- This dialyzer is sterile and nonpyrogenic, sterilized by Gamma ray,which shall be checked before use. To avoid infection, do not use the expired product.Do not use the product if the package is damaged.
- This dialyzer is for single use 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.
- If abnormal conditions arise during the dialysis, such as bubbles ,foreign body ,blood leak, clotting, or hemolysis, proper measures shall be taken according to doctor's advice.
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Instructions for Installation

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   Note: Do not turn off the air monitor system before blood returns completely to prevent the air flowing into the patient from the blood line.

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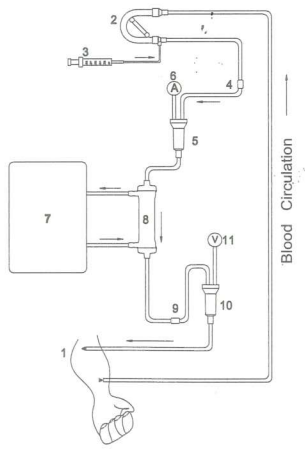

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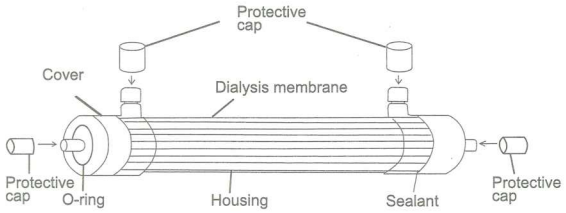

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Note: The laboratory data of this dialyzer was measured according to the standards ISO 8637.

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Main Structure:

Component	Housing	Dialysis membrane	Cover	O-ring	Sealant	Protective cap
Material	Polycarbonate	PES membrane	Polycarbonate	Silicone Resin	Polyurethane	Polypropylene

Model	DIA 13L			DIA 15L			DIA 17L			DIA 19L			DIA 21L		
Product ref.	VHL13			VHL15			VHL17			VHL19			VHL21		
Test Conditions: Q_D = 500mL/min, temperature: 37℃±1℃, Q_F=0 mL/ min															
Clearance / Q_B (mL/min)	200	300	400	200	300	400	200	300	400	200	300	400	200	300	400
Urea (mL/min)	188	253	277	191	260	287	194	267	294	197	274	301	199	279	306
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Phosphate (mL/min)	151	177	198	158	197	219	165	199	238	169	204	246	173	209	260
Vitamin B_{12} (mL/min)	98	109	118	105	113	124	109	127	139	113	134	147	116	139	152
KOA(Urea)	861			961			1083			1239			1382		
Pressure drop of blood compartment (mmHg)	<50	<60	<80	<45	<55	<75	<40	<50	<70	<40	<45	<70	<40	<40	<70
Pressure drop of dialysate compartment (mmHg) Q_D=500mL/min	<35			<40			<45			<45			<45		
Ultrafiltration Coefficient (mL/hr/ mmHg) Q_B=300mL/min, TMP=50mmHg	16			18			19			21			23		
Priming volume (mL)	78			86			100			108			115		
Effective membrane area (㎡).	1.3			1.5			1.7			1.9			2.1		

Special Storage Conditions and Methods: Please avoid crash and exposure to rain, snow, and direct sunlight during transportation. Please store it in a well-ventilated indoor place with storage temperature of 0℃-40℃, with relative humidity no more than 80% and without corrosive gas. DO NOT store it in a warehouse together with chemicals and humid articles.

Shelf life: 3 years after the sterilization date.

After-sale service: if any product inquire is needed, due to manufacturing quality problem, please keep the primary package of the product for product tracing.

EC REP <EU Representative>

MT Promedt Consulting GmbH
Altenhofstrasse 80 D-66386 St. Ingbert, Germany
Tel:+49(0)6894581020 Fax:+49(0)6894581021

<Manufacturer>

VITAL HEALTHCARE SDN.BHD
Lot 3, Jalan Sultan Mohamed 3, Bandar Sultan Sulaiman, 42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia.
Tel:+603 3179 0722 Fax:+603 3179 0822

Distributor: **Proses Medikal Analitik Sistemler Pazarlama Sanayi ve Ticaret A.S.**
Adres : Cetin Emec Bulvarı 1065. Cadde No:12/1-1-3-4-A 06460 Asagı Ovecler/Ankara - Turkey
Tel : 0312 472 15 55 Fax : 0312 472 15 56

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

VH-AW0304G Rev 0 of 2015.7.23

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Vital Healthcare
Sdn. Bhd.
Lot 3, Jalan Sultan Mohamed 3
Bandar Sultan Sulaiman
42000 Pelabuhan Klang, Selangor Darul Ehsan
Malaysia**

has established and applies a quality management system for medical devices for the following scope:

Design and Development, Manufacture and Distribution of Medical Devices (see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2017-12-27
Certificate Registration No.:	SX 60124196 0001
An audit was performed. Report No.:	17042992 004
This Certificate is valid until:	2020-12-25

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2017-12-27

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60124196 0001
Report No.: 17042992 004

Organization:
Vital Healthcare
Sdn. Bhd.
Lot 3, Jalan Sultan Mohamed 3
Bandar Sultan Sulaiman
42000 Pelabuhan Klang, Selangor Darul Ehsan
Malaysia

Scope:

Products:

Tubing Sets for Hemodialysis, Disposable AV Fistula Needle Sets, Disposable AV Fistula Needle Sets (Dull Needle series), Disposable AV Fistula Needle Sets (Safety Needle series), Hollow Fiber Dialyzers, Plasmafilters, Tubing Sets for Blood Purification, Hemofilters, Hemodialysis Bicarbonate

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2017-12-27

X. Ren

EC Declaration of Conformity

Manufacturer:
VITAL HEALTHCARE SDN.BHD.
Address: Lot 3, Jalan Sultan Mohamed 3,
Bandar Sultan Sulaiman, 42000 Pelabuhan Klang,
Selangor Darul Ehsan, Malaysia

EU Representative:
MT Promedt Consulting GmbH
Address: Altenhofstrasse 80 D-66386 St. Ingbert, Germany .
Phone:++49-6894-581020
Fax:++49-6894-581021
DIMDI No.: DE/0000040838

We, the manufacturer, herewith declare that the products

Hollow Fiber Dialyzer

*(*including system components and accessories*)*

UMDNS-Code: 11-234 ; GMDN-Code:35004

Model codes: DIA13L, DIA15L, DIA17L, DIA19L, DIA21L

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIb according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.:HD 600972580001
Issue date: 2015.03.04
Expiry date: 2019.12.25

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: VITAL HEALTHCARE SDN.BHD.

Address: Lot 3, Jalan Sultan Mohamed 3, Bandar Sultan Sulaiman, 42000 Pelabuhan Klang, Selangor Darul Ehsan, Malaysia

GUANGZHOU 2015-03-19
Place , date

Mu Fangzhen, Management Representative
Legally binding signature, Function