EC CERTIFICATE

Number: 3804606CE01

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)
(Devices in Class IIa, IIb or III)

Manufacturer:
Cytosorbents, Inc.
7 Deer Park Dr., Suite K
Monmouth Jct. NJ 08852
United States Of America

For the product category(ies)

Polymer Based Adsorption Systems

DEKRA grants the right to use the EC Notified Body identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EC-Directive which apply to them.

0344

Documents, that form the basis of this certificate:
Certification Notice 3804606CN, initially dated 20 September 2010
Addendum, initially dated 25 March 2011

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant provisions of 'Besluit Medische Hulpmiddelen', the Dutch transposition of the Council Directive 93/42/EEC of June 14, 1993 concerning Medical devices, including all subsequent amendments. The manufacturer has implemented a quality assurance system for design, manufacture and final inspection for the above mentioned product category in accordance to the provisions of Annex II of Council Directive 93/42/EEC of June 14, 1993 and is subject to periodical surveillance. For placing on the market of Class III devices an additional EC design examination certificate according to Annex II (4) is mandatory. The necessary information related to the quality management system of the manufacturer, including facilities and the reference to the relevant documentation, of the products concerned and the assessments performed, are stated in the Certification Notice which forms an integrative part of this certificate.

This certificate is valid until: 1 September 2019
Issued for the first time: 25 March 2011
Reissued: 1 September 2016

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

CONFORM CU ORIGINALUL

ADDENDUM

Belonging to certificate: 3804606CE01

CE MARKING OF CONFORMITY
MEDICAL DEVICES

Polymer Based Adsorption Systems

Issued to:

Cytosorbents, Inc.
7 Deer Park Dr., Suite K
Monmouth Jct. NJ 08852
United States Of America

This certificate covers the following product(s):

Cytokine, Bilirubin, and Myoglobin, Adsorption (Class IIb)

Initial date: 25 March 2011
Revision date: 9 June 2018

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

CERTIFICAT CE

Numărul: 3804606CE01
Sistemul Complet pentru Asigurarea Calităţii
Directiva 93/42/CEE privind Dispozitivele Medicale, Anexa II excluzând (4)
(Dispozitivele din Clasele IIa, IIb sau III)

Producător:
Cytosorbents, Inc.
7 Deer Park Dr., Suite K
Monmouth Jct. NJ 08852
Statele Unite ale Americii

Pentru categoria(categoriile) de produse

Sisteme de Absorbţie pe Bază de Polimeri

DEKRA oferă dreptul de a utiliza Numărul de Identificare al Organismului Notificat CE de mai jos pentru a însoţi Marca de Conformitate CE a produselor implicate care sunt conforme cu Documentaţia Tehnică necesară şi îndeplinesc prevederile Directivei CE care se aplică acestora:

0344

Documentele care stau la baza acestui certificat:

Notificare de Certificare 3804606CN, iniţială din data de 20 septembrie 2010
Act Adiţional, iniţial din data de 25 martie 2011

DEKRA declară că producătorul menţionat mai sus îndeplineşte prevederile aplicabile ale „Besluit Medische Hulpmiddelen", transpunerea olandeză a Directivei 93/42/CEE din 14 iunie 1993 privind dispozitivele medicale, inclusiv toate modificările ulterioare, şi care pentru categoria de produse menţionată mai sus, Procedura de Evaluare a Conformităţii Anexa II pentru produsele din clasa IIa, este realizată de Producător în conformitate cu prevederile Directivei Consiliului 93/42/CEE din 14 iunie 1993. Pentru plasarea pe piaţă a dispozitivelor din Clasa III, este obligatoriu un certificat suplimentar de examinare a design-ului CE conform Anexei II, secţiunea 4. Informaţiile necesare şi referirea la documentaţia aplicabilă privind produsele implicate şi evaluările realizate, sunt menţionate în Notificarea de Certificare care constituie o parte integrantă din acest certificat.

Acest certificat este valabil până în data de: 1 septembrie 2019
Data eliberării iniţiale: 25 martie 2011
Reeliberat: 1 septembrie 2016

DEKRA Certification B.V.

drs. G.J. Zoetbrood	ing. A.A.M. Laan
Director Executiv	Director de Certificare
Semnătură indescifrabilă	*Semnătură indescifrabilă*

DEKRA Certification B.V. este un Organism Notificat cu ID nr. 0344
DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O Box 5185 6802 ED Arnhem. Olanda
T+31 88 96 83000 F+31 88 96 83100 www.dekra-certification.com Nr. de înregistrare a societăţii 09085396

ANEXĂ

Atașată la certificatul cu nr. 3804606CE01

DECLARAȚIE DE CONFORMITATE CE

DISPOZITIVE MEDICALE

Sisteme de absorbție pe bază de polimer

Emis către:

Cytosorbents Imc.
7 Deer Park Dr., Suite K
Monmouth Jct. NJ 08852
Statele Unite ale Americii

Acest certificat acoperă următoarele produse:

Citokină, bilirubină, mioglobină, absorbție (clasa IIb).

Data inițială de emitere: 25 martie 2011

Data revizuirii: 9 iunie 2018

DEKRA Certification B.V.

semnătură indescifrabilă	*semnătură indescifrabilă*
Dr. G. J. Zoetbrood	Ing. A. A. M. Laan
Director general	Manager de certificare

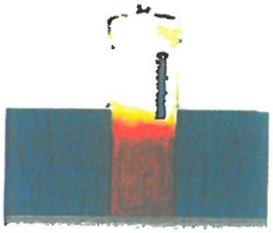
DEKRA Certification B.V. este un organism notificat cu nr. 0344

DEKRA Certification B.V. Meander 1051, 8825 MJ Amhem Cod poștal 5185, 6802 ED Amhem, Olanda

T +31 88 96 83000 F +88 96 83100 www.dekra-certification.com Nr. de înregistrare 09085396

MIHAELA BALTĂ

CytoSorbents
7 Deer Park Drive, Suite K
Monmouth Junction, NJ 08852
Phone: (732) 329-8885
Fax: (732) 329-8650
www. CytoSorbents.com



Declaration of Conformity
Polymer Based Adsorption Systems

We hereby declare that the distributed CE marked products, specified in the annexed product list, conform to the product(s) covered by:

CE Marking of Conformity Certificate Reference #3804606CE01	
Description	**Date**
Initial Certification	March 25, 2011
Renewal	September 01, 2013
Renewal	September 01, 2016

Delivered by DEKRA Certification Inc., Arnhem, The Netherlands, Notified Body Identification Number 0344, in accordance with Annex II of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class IIb, meet the provisions of the EC-Directive which apply to them.

This declaration is based on the application of the Quality System approved for the design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive. The conformity of the full quality assurance system set out in Annex II, is described in the said CE Marking of Conformity Certificate, issued and delivered by DEKRA Certification Inc.

7 Deer Park Drive, Suite K
Monmouth Junction, NJ 08852
United States of America

This Declaration of Conformity covers Polymer Based Adsorption Systems as specified in the product list belonging to this declaration, and is valid for all products concerned bearing the CE marking and manufactured at the following site:

CytoSorbents Inc.
7 Deer Park Drive
Suite K
Monmouth Junction, NJ 08852
United States of America

Retaining the EC Authorized Representative:

MedPass International Limited
Windsor House
Bretforton, Evesham, Worcestershire
WR11 7JJ
United Kingdom

Vincent Capponi
Chief Operations Officer

CytoSorbents Incorporated 7 Deer Park Drive Suite K Monmouth Junction New Jersey 08852 www.CytoSorbents.com

9/7/16 Date

Annex: Product List

CytoSorb 300 mL Device

CytoSorbents
7 Deer Park Drive, Suite K
Monmouth Junction, NJ08852
Telefon: (732) 329-8885
Fax: (732) 329-86.50
www.CytoSorbents.com

Declarație de Conformitate
Sisteme de Absorbție pe Bază de Polimeri

Declarăm prin prezenta că produsele Distribuite care poartă marca CE din lista produselor atașată sunt conforme cu produsele acoperite de:

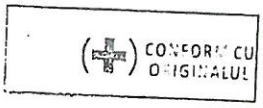
Marca CE a Certificatului de Conformitate Nr. de referință 3804606CE)1	
Descriere	**Data**
Certificare Inițială	**25 martie 2011**
Reînnoire	**1 septembrie 2013**
Reînnoire	**1 septembrie 2016**

Livrată de DEKRA Certification Inc., Arnhem, Olanda, Numărul de Identificare al Organismului Notificat 0344, conform Anexei II la Directiva CE, Directiva Consiliului 93/42/CEE din 14 iunie 1993 privind dispozitivele medicale.

De asemenea, asigurăm și declarăm că produsele distribuite marcate CE așa cum sunt menționate și care sunt clasificate în Clasa IIb îndeplinesc prevederile Directive CE care se aplică acestora.

Această declarație se bazează pe cererea Sistemului de Calitate aprobată pentru proiectarea, fabricarea și inspecția finală a produselor vizate conform Anexei II din Directiva CE. Conformitatea sistemului complet de asigurare a calității prevăzută în Anexa II este descrisă în Marcarea CE a Certificatului de Conformitate, emisă și livrată de DEKRA Certification Inc.

Data eliberării: 7 septembrie 2016



CytoSorbents

7 Deer Park Drive, Suite K
Monmouth Junction, NJ08852
Statele Unite ale Americii

Această Declarație de Conformitate acoperă Sistemele de Absorbție pe Bază de Polimeri de pe lista produselor asociată acestei declarații și este valabilă pentru toate produsele vizate care poartă marca CE și fabricate la următoarea unitate:

CytoSorbents
7 Deer Park Drive
Suite K
Monmouth Junction, NJ 08852
Statele Unite ale Americii

Reprezentantul Autorizat CE:

MedPass International Limited
Windsor House
Bretforton, Evesham, Worcestershire
WR11 7JJ
Regatul Unit

Semnătură indescifrabilă
Ștampilă rotundă: CytoSorbents Incorporated

Vincent Capponi
Director Operațional

Anexa: Lista Produselor
Dispozitiv CytoSorb de 300 mL

Data eliberării: 7 septembrie 2016

CERTIFICATE

Number: 3804606

The management system of:

Cytosorbents, Inc.

7 Deer Park Dr., Suite K
Monmouth Jct. NJ 08852
United States Of America

including the implementation meets the requirements of the standard:

ISO 13485:2003

Scope:
Design, development, manufacture and distribution of selectively adsorbent polymer cartridges for dialysis of physiological fluids for the area of extracorporeal therapy and accessory clamps.

Certificate expiry date: 31 December 2018
Certificate effective date: 20 September 2016
Certified since: 20 September 2010

DEKRA Certification B.V.

drs. G.J. Zoetbrood
Managing Director

ing. A.A.M. Laan
Certification Manager

DEKRA Certification B.V. is a CMDCAS recognized registrar.

SCC Accredited CB-MS

Accredited by:
Standards Council of Canada

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra-certification.com Company registration 09085396

CERTIFICAT

Nr. 3804606
Sistemul de Gestionare al societății:

CytoSorbents Corp.
7 Deer Park Dr., Suite K
Monmouth Jct., NJ 08852
SUA
inclusiv implementarea, respectă cerințele standardului:
ISO 13485:2003

Domeniu de aplicare:
Proiectarea, dezvoltarea, fabricarea și distribuția de cartușe cu polimeri cu adsorbție selectivă pentru dializa lichidelor fiziologice pentru domeniul terapiei extracorporale.

Data de expirare a certificatului: 20 septembrie 2016
Data de intrare în vigoare a certificatului: 20 septembrie 2013
Prima certificare: 20 septembrie 2010

DEKRA Certification BV

Semnătură indescifrabilă	*Semnătură indescifrabilă*
drs. G.J. Zoetbrood	Ing. A.A.M. Laan
Director General	Manager de Certificare

Acreditat de:
Consiliul de Standarde al Canadei
Marcă înregistrată deținută de Consiliul de Standarde al Canadei, utilizată cu permisiunea acestuia

DEKRA Certification BV, Utrechtsweg 310, 6812 AR Arnhem, CP 5185, 6802 ED Arnhem, Țările de Jos
T +31 88 96 83000 F: +31 88 96 83100 www.dekra-certification.com
Nr. de înregistrare al societății: 09085396

EC CERTIFICATE

for the Quality Assurance System

according the directive 93/42/EEC, Annex II excluding section (4)

As a notified body of the European Union, DEKRA Certification GmbH certifies that the company

JOLINE GmbH & Co. KG

Neue Rottenburger Straße 50, 72379 Hechingen, Germany

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex II. The approval is based on the result of the re-certification audit report no. 50565-Z4-00, the decision dated 2015-11-25 is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2015-11-30 to 2018-11-29

Certificate registration No.: 50565-16-05

DEKRA Certification GmbH Stuttgart; 2015-11-25
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

Annex to the EC Certificate 50565-16-05 dated 2015-11-25

Devices / device categories included in the certificate

Class II a:

MD 0102

- Dialysis Catheter ST
  - Kits
  - Catheter

MD 0106

- Kyphoplasty Systems ALLEVO
  - Kits
  - Individual Instruments
- Dialysis Accessories
  - Introducer Needle
  - Guide Wire
  - Dilator
  - Trocar
  - Split Sheath
  - Connektor LT
  - Suture Wing Silicone LT
  - Repair Kit
  - Straightening Stylette

Class II b

MD 0203

- Peritoneal Catheter
  - Kits
  - Catheter

Class III

MD 0203

- Dialysis Catheter PU-LT
  - Kits
  - Catheter
- Dialysis Catheter Silikon LT
  - Kits
  - Catheter

MD 0106

- Biopsy Forceps KNIPSA

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

CERTIFICAT CE
pentru Sistemul de Asigurare a Calității

conform directivei 93/42/CEE,
Anexa II excluzând secțiunea (4)

În calitate de organism notificat al Uniunii Europene, DEKRA Certification GmbH atestă că societatea

JOLINE GmbH & Co. KG

Neue Rottenburger Straße 50, 72379 Hechingen, Germania

aplică un sistem de asigurare a calității pentru dispozitivele medicale prevăzute în anexă conform directivei 93/42/CEE anexa II. Aprobarea se bazează pe rezultatul raportului auditului pentru recertificare nr. 50565-Z4-00, decizia din data de 25.11.2015 este valabilă doar cu condiția trecerii cu succes a auditurilor de supraveghere anuală.

Prezentul certificat este valabil în perioada 30.11.2015-29.11.2018
Nr. de înregistrare a certificatului: 50565-16-05

DEKRA Certification GmbH Stuttgart, 25.11.2015
Semnătură indescifrabilă
Nr. Organism Notificat: 0124
DEKRA Certification GmbH * Handwekstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

Anexa la Certificatul CE 50565-16-05 din data de 25.11.2015

Starea de Revizuire: 0 Data: 30.11.2015 Pagina 1 din 1

Categorii de dispozitive/dispozitiv inclus/e în certificat

Clasa II a:
MD 0102
- Cateter Dializă ST
  - Kituri
  - Cateter

MD 0106
- Sisteme de Kifoplastie ALLEVO
  - Kituri
  - Instrumente Individuale
- Accesorii pentru Dializă
  - Ac Introducere
  - Cablu de Ghidare
  - Dilatator
  - Trocar
  - Înveliș Despărțitor
  - Conector LT
  - Silicon Aripă Sutură LT
  - Kit de Reparare
  - Stilet de Îndreptare

Clasa II b
MD 0203
- Cateter Peritoneal
  - Kituri
  - Cateter

Clasa III
MD 0203
- Cateter Dializă PU-LT
  - Kituri
  - Cateter
- Silicon Cateter Dializă LT
  - Kituri
  - Cateter

MD 0106
- Forceps Biopsie KNIPSA

Pentru punerea pe piață a dispozitivelor din clasa III acoperite de acest certificat este necesar un certificat de examinare proiectare CE conform directivei 93/42/CEE anexa II (4).

EC CERTIFICATE

for the Quality Assurance System

according the directive 93/42/EEC, Annex V

As a notified body of the European Union, DEKRA Certification GmbH certifies, that the company

JOLINE GmbH & Co. KG

Neue Rottenburger Straße 50, 72379 Hechingen, Germany

applies a quality assurance system for the medical devices listed in the annex according to the directive 93/42/EEC annex V. The approval is based on the result of the re-certification audit report no. 50565-Z4-00, the decision dated 2015-11-25 is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2015-11-30 to 2018-11-29

Certificate registration No.: 50565-17-04

DEKRA Certification GmbH Stuttgart; 2015-11-25
Notified Body ID-number: 0124

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-BS-295.10.02

DEKRA Certification GmbH * Handwerkstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

Annex to the EC Certificate 50565-17-04 dated 2015-11-25

Revision status: 0 Date: 2015-11-30

Devices / device categories included in the certificate

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

MD 0101

- Protective Cap/ Luer Lock Injection Cap
- Miniclamp

MD 0106

- Stone Extraction Catheter
- Application Catheter for Bile Duct Endoprostheses
- Sinuplasty Kit LENIO
  - Kits
  - Catheter
- Mixer

CERTIFICAT CE
pentru Sistemul de Asigurare a Calității

conform directivei 93/42/CEE,
Anexa II excluzând secțiunea (4)

În calitate de organism notificat al Uniunii Europene, DEKRA Certification GmbH atestă că societatea

JOLINE GmbH & Co. KG

Neue Rottenburger Straße 50, 72379 Hechingen, Germania

aplică un sistem de asigurare a calității pentru dispozitivele medicale prevăzute în anexă conform directivei 93/42/CEE anexa V. Aprobarea se bazează pe rezultatul raportului auditului pentru recertificare nr. 50565-Z4-00, decizia din data de 25.11.2015 este valabilă doar cu condiția trecerii cu succes a auditurilor de supraveghere anuală.

Prezentul certificat este valabil în perioada 30.11.2015-29.11.2018
Nr. de înregistrare a certificatului: 50565-17-04

DEKRA Certification GmbH Stuttgart, 25.11.2015
Semnătură indescifrabilă
Ștampilă rotundă: DEKRA Certification GmbH
Nr. Organism Notificat: 0124
DEKRA Certification GmbH * Handwekstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

Anexa la Certificatul CE 50565-16-05 din data de 25.11.2015

Starea de Revizuire: 0 Data: 30.11.2015 Pagina 1 din 1

Categorii de dispozitive/dispozitiv inclus/e în certificat

Clasa I s:
Pentru produsele de mai jos, revizuirea Sistemului de Asigurare a Calității se referă exclusiv la aspectele legate de producție care se referă la asigurarea și menținerea condițiilor sterile.

MD 0101

- Capac Protectiv/Capac de Injecție Blocare Luer
- Mini-clemă

MD0106

- Cateter Extracție Pietre
- Cateter Aplicare pentru Endoproteze Canalul Biliar
- Sinuplastie KIT LENIO
  - Kituri
  - Cateter
- Mixer

Joline®

JOLINE GmbH & Co. KG • Neue Rottenburger Str. 50 • D-72379 Hechingen

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

Name und Adresse der Firma / Name and address of the firm

Joline GmbH & Co. KG
Neue Rottenburger Straße 50
D - 72379 Hechingen
Germany

Wir erklären in alleiniger Verantwortung, dass das Medizinprodukt /
We declare under our sole responsibility that the medical device

Dialyse Katheter ST gemäß Anhang /
Dialysis Catheter ST according to the annex

der Klasse IIa / of class IIa
nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of direct. 93/42/EEC

allen Anforderungen der Medizinprodukte-Richtlinie 93/42/EWG entspricht, die anwendbar sind /
meets all the provisions of the directive 93/42/EEC which apply to it.

Konformitätsbewertungsverfahren / Conformity assessment procedure

Nach Anhang II, vollständiges Qualitätssicherungssystem /
According to Annex II, complete quality assurance system

Konformitätsbewertungsstelle / Notified Body

DEKRA Certification GmbH
Handwerkstrasse 15
D-70565 Stuttgart
Germany
ID: CE 0124

Diese Erklärung ist gültig bis zum 29.11.2018 bzw. bis zur Ausstellung einer revidierten Erklärung. /
This declaration is valid until 2018-11-29 or until a revised declaration comes into effect.

Hechingen, 28.09.16 / 2016-09-28

Michael Eisenlohr
Site Manager

Dr. Marien Wenzel
Director QA/RA

R06

Joline®

JOLINE GmbH & Co. KG • Neue Rottenburger Str. 50 • D-72379 Hechingen

ANHANG – PRODUKTLISTE / ANNEX – PRODUCT LIST

Single Lumen Short Term

DCP 8/12,5 PH	KSL08P200 21	SL08P100C	SL08PH100CD
DCP 8/15 H	KSL08P200C	SL08P100CD	SL08PH100D
DCP 8/15 H-PH	KSL08P225	SL08P100D	SL08PH125
DCP 8/15 PH	KSL08P225C	SL08P125	SL08PH125C
DCP 8/17,5 H-PH	KSL08P250	SL08P125C	SL08PH125CD
DCP 8/17,5 PH	KSL08P250C	SL08P125CD	SL08PH125D
DCP 8/20	KSL08PH100	SL08P125D	SL08PH150
DCP 8/20 PH	KSL08PH100C	SL08P150	SL08PH150C
DCP 8/25 PH	KSL08PH125	SL08P150C	SL08PH150CD
DCPT 8/10	KSL08PH125C	SL08P150CD	SL08PH150D
DCPT 8/15	KSL08PH150	SL08P150D	SL08PH175
DCPT 8/15 H-PH	KSL08PH150C	SL08P175	SL08PH175C
DCPT 8/15 PH	KSL08PH175	SL08P175C	SL08PH175CD
DCPT 8/17,5 H-PH	KSL08PH175C	SL08P175CD	SL08PH175D
DCPT 8/17,5 PH	KSL08PH200	SL08P175D	SL08PH200
DCPT 8/20 H-PH	KSL08PH200C	SL08P200	SL08PH200C
DCPT 8/20 PH	KSL08PH225	SL08P200C	SL08PH200CD
KSL08P100	KSL08PH225C	SL08P200CD	SL08PH200D
KSL08P100C	KSL08PH250	SL08P200D	SL08PH225
KSL08P125	KSL08PH250C	SL08P225	SL08PH225C
KSL08P125C	PKSL08P150	SL08P225C	SL08PH225CD
KSL08P150	PKSL08P150C	SL08P225CD	SL08PH225D
KSL08P150	PKSL08P175	SL08P225D	SL08PH250
KSL08P150 21	PKSL08P175C	SL08P250	SL08PH250C
KSL08P150C	PKSL08P200	SL08P250C	SL08PH250CD
KSL08P150C 21	PKSL08P200C	SL08P250CD	SL08PH250D
KSL08P175	PKSL08P250	SL08P250D	
KSL08P175C	PKSL08P250C	SL08PH100	
KSL08P200	SL08P100	SL08PH100C	

Single Lumen ST (Händler / Distributor)

-PKSL08P150	Single Lumen	ST
-PKSL08P175	Single Lumen	ST
-PKSL08P200	Single Lumen	ST
-PKSL08P250	Single Lumen	ST

R08

Joline®

JOLINE GmbH & Co. KG • Neue Rottenburger Str. 50 • D-72379 Hechingen

Double Lumen Short Term High Flow Kits

HF-DLS 13/15
HF-DLS 13/15 C
HF-DLS 13/17,5
HF-DLS 13/17,5 C
HF-DLS 13/20
HF-DLS 13/20 C
HF-DLS 13/25
KHF13PH100
KHF13PH125
KHF13PH125C
KHF13PH125R
KHF13PH150
KHF13PH150 21
KHF13PH150C
KHF13PH150C 21
KHF13PH150R
KHF13PH150R 21
KHF13PH175
KHF13PH175 21
KHF13PH175C
KHF13PH175C 21
KHF13PH175R
KHF13PH200
KHF13PH200 21
KHF13PH200C
KHF13PH200C 21
KHF13PH200R
KHF13PH225
KHF13PH225 21
KHF13PH225C
KHF13PH225R
KHF13PH225R 21
KHF13PH250
KHF13PH250 21
KHF13PH250C 21
KHF13PH250R
PKHF13PH125
PKHF13PH125R
PKHF13PH150
PKHF13PH150C 21
PKHF13PH150R
PKHF13PH175
PKHF13PH175R
PKHF13PH200
PKHF13PH200R
PKHF13PH250
PKHF13PH250R

High Flow Double Lumen ST (Händler / Distributor)

-PKHF13PH150	High Flow Double Lumen ST	w. Stylet
-PKHF13PH175	High Flow Double Lumen ST	w. Stylet
-PKHF13PH200	High Flow Double Lumen ST	w. Stylet
-PKHF13PH250	High Flow Double Lumen ST	w. Stylet
-PKHF13PH150R	High Flow Double Lumen ST	w. Stylet Curved
-PKHF13PH175R	High Flow Double Lumen ST	w. Stylet Curved
-PKHF13PH200R	High Flow Double Lumen ST	w. Stylet Curved
-PKHF13PH250R	High Flow Double Lumen ST	w. Stylet Curved

Double Lumen Extra Flow - Pädiatrisch

KDL06P075
KDL06P075 21
KDL06P075C
KDL06P075C 21
KDL06P075R
KDL06P075R 21
KDL06P100
KDL06P100 21
KDL06P100C
KDL06P100R
KDL06P100R 21
KDL06P125
KDL06P125C
KDL06P125R
KDL06P150
KDL06P150 21
KDL08P075
KDL08P075C
KDL08P075R
KDL08P100
KDL08P100C
KDL08P100R
KDL08P100R 21
KDL08P125
KDL08P125 21
KDL08P125C
KDL08P125C 21
KDL08P125R
KDL08P150
KDL08P150 21
KDL08P150C
P-DLS 6,5/10
P-DLS 6,5/10 C
P-DLS 6,5/7,5
P-DLS 6,5/7,5 C
P-DLS 8/15
PKDL06P075
PKDL06P075R
PKDL06P100
PKDL06P100R
PKDL06P125
PKDL06P125R
PKDL08P075 21
PKDL08P100
PKDL08P100R
PKDL08P125
PKDL08P125R
PKDL08P150
PKDL08P150 21
PKDL08P150R

Extra Flow Double Lumen (Händler / Distributor)

-PKDL08P100	Extra Flow Double Lumen	ST
-PKDL08P125	Extra Flow Double Lumen	ST
-PKDL08P150	Extra Flow Double Lumen	ST
-PKDL08P100R	Extra Flow Double Lumen ST	Curved
-PKDL08P125R	Extra Flow Double Lumen ST	Curved
-PKDL08P150R	Extra Flow Double Lumen ST	Curved
-PKDL06P075	Extra Flow Double Lumen	ST
-PKDL06P100	Extra Flow Double Lumen	ST
-PKDL06P125	Extra Flow Double Lumen	ST
-PKDL06P075R	Extra Flow Double Lumen ST	Curved
-PKDL06P100R	Extra Flow Double Lumen ST	Curved
-PKDL06P125R	Extra Flow Double Lumen ST	Curved

R06

Joline®

JOLINE GmbH & Co. KG • Neue Rottenburger Str. 50 • D-72379 Hechingen

Double Lumen Silicone Short Term

KEFS250	PKEFS250
KEFS250 N	PKEFS250 N
KEFS250 N 21	PKEFS250 N 21
KEFS300	PKEFS300
KEFS300 N	PKEFS300 N
KEFS300 N 21	PKEFS350
KEFS350	PKEFS350 N
KEFS350 N	

Double Lumen ST (Händler / Distributor)

-PKEFS250	Double Lumen	ST
-PKEFS300	Double Lumen	ST
-PKEFS350	Double Lumen	ST

Double Lumen Short Term Precurved

HF-DLS 13/15 R	PKHFP13PH200
HF-DLS 13/20 R	PKHFP13PH150
	PKHFP13PH150 21
	PKHFP13PH250

High Flow Double L. ST (Händler / Distributor)

-PKHFP13PH150	High Flow Double L. ST.	Curved w. Stylet
-PKHFP13PH200	High Flow Double L. ST.	Curved w. Stylet
-PKHFP13PH250	High Flow Double L. ST.	Curved w. Stylet

Triple Lumen Short Term

TL12P125	TL12P225D	TLK 12/15	PKTL12P150
TL12P125C	TL12P225CD	TLK 12/15 H	PKTL12P200
TL12P125D	TL12P250	TLK 12/17,5	KTL12P150 21
TL12P125CD	TL12P250C	TLK 12/17,5 H	PKTL12P150C
TL12P150	TL12P250D	TLK 12/20	KTL12P150C 21
TL12P150C	TL12P250CD	TLK 12/20 H	KTL12P250 21
TL12P150D	KTL12P125	TLK 12/25	PKTL12P200C 21
TL12P150CD	KTL12P125C	KTL12P125R	PKTL12P175
TL12P175	KTL12P150	KTL12P150R	PKTL12P175C
TL12P175C	KTL12P150C	KTL12P175R	PKTL12P150 C 21
TL12P175D	KTL12P175	KTL12P200R	PKTL12P175 21
TL12P175CD	KTL12P175C	TLK 12/15 C	PKTL12P200 21
TL12P200	KTL12P200	TLK 12/17,5 C	PKTL12P175C 21
TL12P200C	KTL12P200C	TLK 12/20 C	PKTL12P250R
TL12P200D	KTL12P225	KTL12P200 21	PKTL12P250
TL12P200CD	KTL12P225C	KTL12P175 21	PKTL12P150R
TL12P225	KTL12P250	KTL12P200C 21	PKTL12P175R
TL12P225C	KTL12P250C	KTL12P175C 21	PKTL12P200R

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Joline®

JOLINE GmbH & Co. KG • Neue Rottenburger Str. 50 • D-72379 Hechingen

Double Lumen Short Term Extra Flow Kits

HF-DLS 11/12,5
HF-DLS 11/12,5 C
HF-DLS 11/15
HF-DLS 11/15 C
HF-DLS 11/15 C 14
HF-DLS 11/17,5
HF-DLS 11/17,5 C
HF-DLS 11/20
HF-DLS 11/20 C
HF-DLS 11/20 C 14
HF-DLS 11/22,5
HF-DLS 11/25
HF-DLS 11/25 C
HF-DLS 11/25 C 14
HF-DLS 11/30
KDL08P100R 21
KEF11P100
KEF11P100C
KEF11P125
KEF11P125C
KEF11P125R
KEF11P150
KEF11P150 21
KEF11P150C
KEF11P150C 21
KEF11P150R
KEF11P150R 21
KEF11P175
KEF11P175 21
KEF11P175C
KEF11P175C 21
KEF11P175R
KEF11P175R 21
KEF11P200
KEF11P200 21
KEF11P200C
KEF11P200C 21
KEF11P200R
KEF11P200R 21
KEF11P225
KEF11P225 21
KEF11P225C
KEF11P225R
KEF11P225R 21
KEF11P250
KEF11P250 21
KEF11P250C
KEF11P250R
KEF11P300
KEF11P300 21
KEF11P300C
KEF11P300R
KEF11P300R 21
KEF11PH125R
KEF11PH150C
KEF11PH150R
KEF11PH175
KEF11PH175 21
KEF11PH175C 21
KEF11PH175R
KEF11PH200
KEF11PH200 21
KEF11PH200C
KEF11PH200C 21
KEF11PH200R
KEF11PH250
KEF11PH300
PKEF11P125R
PKEF11P150
PKEF11P150C 21
PKEF11P150R
PKEF11P150R 21
PKEF11P175
PKEF11P175 21
PKEF11P175C 21
PKEF11P175R
PKEF11P175R 21
PKEF11P200
PKEF11P200 21
PKEF11P200R
PKEF11P200R 21
PKEF11P225
PKEF11P225R
PKEF11P250
PKEF11P250R
PKEF11P300
PKEF11P300 21
PKEF11P300R
PKEF11PH175R
PKEF11PH200R
PKEF11PH250
PKHF11P125
PKHF11P125R
PKHF11P150
PKHF11P150R
PKHF11P150R 21
PKHF11P175
PKHF11P175R
PKHF11P200
PKHF11P200R
PKHF11P225
PKHF11P225R
PKHF11P250
PKHF11P250R

Double Lumen ST Extra Flow (Händler / Distributor)

-PKHF11P150	High Flow Double Lumen ST	w. Stylet
-PKHF11P175	High Flow Double Lumen ST	w. Stylet
-PKHF11P200	High Flow Double Lumen ST	w. Stylet
-PKHF11P250	High Flow Double Lumen ST	w. Stylet
-PKHF11P150R	High Flow Double Lumen ST	w. Stylet Curved
-PKHF11P175R	High Flow Double Lumen ST	w. Stylet Curved
-PKHF11P200R	High Flow Double Lumen ST	w. Stylet Curved
-PKHF11P250R	High Flow Double Lumen ST	w. Stylet Curved
-PKEF11P150	Extra Flow Double Lumen	ST
-PKEF11P175	Extra Flow Double Lumen	ST
-PKEF11P200	Extra Flow Double Lumen	ST
-PKEF11P250	Extra Flow Double Lumen	ST
-PKEF11P150R	Extra Flow Double Lumen ST	Curved
-PKEF11P175R	Extra Flow Double Lumen ST	Curved
-PKEF11P200R	Extra Flow Double Lumen ST	Curved
-PKEF11P250R	Extra Flow Double Lumen ST	Curved

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Double Lumen Short Term Standard - Einzelkatheter und Kits

DL 11/15
DL 11/15 C
DL 11/15 H
DL 11/17,5
DL 11/17,5 C
DL 11/17,5 H
DL 11/20
DL 11/20 C
DL 11/20 H
DL 11/25
DL11P100
DL11P100C
DL11P100CD
DL11P100D
DL11P125
DL11P125C
DL11P125CD
DL11P125D
DL11P150
DL11P150C
DL11P150CD
DL11P150D
DL11P175
DL11P175C
DL11P175CD
DL11P175D
DL11P200
DL11P200C
DL11P200CD
DL11P200D
DL11P225
DL11P225C
DL11P225CD
DL11P225D
DL11P250
DL11P250C
DL11P250CD
DL11P250D
DL11PH125CD
DL11PH125D
DL11PH150C
DL11PH150D
DLS 11/12,5
DLS 11/15
DLS 11/15 C
DLS 11/15 H
DLS 11/17,5
DLS 11/17,5 C
DLS 11/17,5 H
DLS 11/20
DLS 11/20 C
DLS 11/20 H
DLS 11/25
KDL08P150C 21
KDL11P100
KDL11P100C
KDL11P125
KDL11P125C
KDL11P125R
KDL11P130C
KDL11P150
KDL11P150 05
KDL11P150 21
KDL11P150C
KDL11P150C 05
KDL11P150C 21
KDL11P150R
KDL11P150R 21
KDL11P175
KDL11P175 21
KDL11P175C
KDL11P175C 21
KDL11P175R
KDL11P175R 21
KDL11P200
KDL11P200 21
KDL11P200C
KDL11P200C 21
KDL11P200R
KDL11P200R 21
KDL11P225
KDL11P225 21
KDL11P225C
KDL11P225R
KDL11P225R 21
KDL11P250
KDL11P250 21
KDL11P250C
KDL11P250C 21
KDL11P250R
KDL11P250R 21
KDL11PH100R
KDL11PH125
KDL11PH125C
KDL11PH125R
KDL11PH150
KDL11PH150 21
KDL11PH150C
KDL11PH150C 21
KDL11PH150R
KDL11PH150R 21
KDL11PH175
KDL11PH175 21
KDL11PH175C
KDL11PH175C 21
KDL11PH175R
KDL11PH200
KDL11PH200 21
KDL11PH200C
KDL11PH200C 21
KDL11PH200R
KDL11PH200R 21
KDL11PH250
PKDL11P125
PKDL11P125R
PKDL11P150
PKDL11P150 21
PKDL11P150C
PKDL11P150C 21
PKDL11P150R
PKDL11P150R 21
PKDL11P175
PKDL11P175 21
PKDL11P175C
PKDL11P175C 21
PKDL11P175R
PKDL11P175R 21
PKDL11P200
PKDL11P200C
PKDL11P200R
PKDL11P250
PKDL11P250R
PKDL11PH150C 21
PKDL11PH150R 21
PKDL11PH175 21
PKDL11PH175C
PKDL11PH200
PKDL11PH200 21

Double Lumen ST (Händler / Distributor)

-PKDL11P125	Double Lumen	ST
-PKDL11P150	Double Lumen	ST
-PKDL11P175	Double Lumen	ST
-PKDL11P200	Double Lumen	ST
-PKDL11P250	Double Lumen	ST
-PKDL11P125R	Double Lumen ST	Curved
-PKDL11P150R	Double Lumen ST	Curved
-PKDL11P175R	Double Lumen ST	Curved
-PKDL11P200R	Double Lumen ST	Curved
-PKDL11P250R	Double Lumen ST	Curved

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Triple Lumen ST Händler

-PKTL12P150	Triple Lumen	ST
-PKTL12P175	Triple Lumen	ST
-PKTL12P200	Triple Lumen	ST
-PKTL12P250	Triple Lumen	ST
-PKTL12P150R	Triple Lumen ST	Curved
-PKTL12P175R	Triple Lumen ST	Curved
-PKTL12P200R	Triple Lumen St	Curved
-PKTL12P250R	Triple Lumen ST	Curved

Triple Lumen Short Term High Flow

HF-TLK 13/15	HF-TLK 13/30 H	KTHF13P250	PKTHF13P175C
HF-TLK 13/15 C	KTHF13P150	KTHF13P250C	PKTHF13P175R
HF-TLK 13/17,5	KTHF13P150C	KTHF13P250R	PKTHF13P200
HF-TLK 13/17,5 C	KTHF13P150C 21	PKTHF13P125	PKTHF13P200 21
HF-TLK 13/17,5 H	KTHF13P150R	PKTHF13P125R	PKTHF13P200R
HF-TLK 13/20	KTHF13P175 21	PKTHF13P150	PKTHF13P250
HF-TLK 13/20 C	KTHF13P175R	PKTHF13P150 21	PKTHF13P250R
HF-TLK 13/25	KTHF13P200	PKTHF13P150 C 21	THF13P150
HF-TLK 13/25 H	KTHF13P200 21	PKTHF13P150C	THF13P150C
HF-TLK 13/30	KTHF13P200C	PKTHF13P150R	THF13P250
HF-TLK 13/30 C	KTHF13P200R	PKTHF13P175	

Triple Lumen ST Händler

-PKTHF13P150	Triple Lumen	ST
-PKTHF13P175	Triple Lumen	ST
-PKTHF13P200	Triple Lumen	ST
-PKTHF13P250	Triple Lumen	ST
-PKTHF13P150R	Triple Lumen ST	Curved
-PKTHF13P175R	Triple Lumen ST	Curved
-PKTHF13P200R	Triple Lumen ST	Curved
-PKTHF13P250R	Triple Lumen ST	Curved

R06

CERTIFICAT

EN ISO 13485:2012 + AC:2012

DEKRA Certification GmbH atestă că societatea

JOLINE GmbH & Co. KG

Neue Rottenburger Straße 50, 72379 Hechingen, Germania

Obiectul certificării:

Dezvoltarea, producția, marketing-ul și depozitarea produselor de sisteme cateter în domeniul/gama de terapie intensivă, nefrologie, cardiologie, ortopedie și otorinolaringologie [1,2]
Dezvoltarea și fabricarea de stenturi[3]

Locuri certificate:
Neue Rottenburger Straße 48, 72379 Hechingen, Germania[1]
Neue Rottenburger Straße 50, 72379 Hechingen, Germania[2]
Lotzenäcker 3, 72379 Hechingen, Germania[3]

a stabilit și menține un sistem de management al calității conform standardului de mai sus. Conformitatea a fost dovedită prin raportul de audit nr. 50565-Z4-00.

Prezentul certificat este valabil în perioada 30.11.2015 – 29.11.2018

Nr. de înregistrare a certificatului: 50565-11-00

Semnătură indescifrabilă
Ștampilă rotundă: DEKRA Certification GmbH

DEKRA Certification GmbH Stuttgart, 25.11.2015
DEKRA Certification GmbH * Handwekstraße 15 * D-70565 Stuttgart * www.dekra-certification.de

DAkks
Deutsche Akkreditierungsstelle
D-ZM-16029-08-00

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 17 08 66097 082

Manufacturer:

B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
GERMANY

Facility(ies):

B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11, 41037 Mirandola (MO), ITALY

Product Category(ies):

Accessories for dialysis, infusion and apheresis (class I sterile)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 713113517

Valid from: 2018-01-10
Valid until: 2023-01-09

Date, 2017-10-11

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

A1 / 04.11

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 16 06 66097 071

Holder of Certificate: **B. Braun Avitum AG**
Schwarzenberger Weg 73-79
34212 Melsungen
GERMANY

Facility(ies):

B. Braun Avitum AG
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY

B. Braun Avitum AG
Am Buschberg 1, 34212 Melsungen, GERMANY

B. Braun Avitum AG, Werk Glandorf
Kattenvenner Straße 32, 49219 Glandorf, GERMANY

Certification Mark:

Scope of Certificate:

Design and Development, Production, Distribution and Servicing of Active and Non-Active Medical Devices for Extracorporeal Blood Treatment (Hemodialysis, Acute Dialysis, Apheresis);
Design and Development, Production and Distribution of Non-Active Medical Devices in various Therapies;
Distribution and Servicing of Active Medical Devices for Reverse Osmosis Systems, Central Concentrate Supply, Ring Piping and Hot Rinse Disinfection Systems

Applied Standard(s):

EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713078602
Valid from: 2016-08-01
Valid until: 2019-07-31

Date, 2016-07-27

Stefan Preiß

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV®

DAkkS CRT2 / 10.13

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 14 12 66097 065

Manufacturer:

B. Braun Avitum AG
Schwarzenberger Weg 73 - 79
34212 Melsungen
GERMANY

Facility(ies):

B. Braun Avitum AG
Schwarzenberger Weg 73 - 79, 34212 Melsungen, GERMANY

B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11, 41037 Mirandola (MO), ITALY

B. Braun Medical Kft Production Division
Déli-Külhatár út 2-4, 3200 Gyöngyös, HUNGARY

B. BRAUN Vietnam Co., Ltd.
Thanh Oai Industrial Complex, Thanh Oai District, 156800 Hanoi, VIETNAM

Product Category(ies):

Kit for Dialysis and Haemo(dia)filtration (extracorporeal circuit and dialyser)
Lines for Dialysis and Hemo(dia)filtration

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713053585

Valid from: 2015-06-23
Valid until: 2020-06-22

Date, 2014-12-18

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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A1 / 04.11

ERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Traducere din limba engleză

CERTIFICAT CE
SISTEMUL COMPLET DE ASIGURARE A CALITATII

(Directiva 93/42/CEE privind Dispozitivele medicale), Anexa II excluzând (4)
(Dispozitive in clasa IIa, IIb sau III)
Număr G1 14 12 66097 065

Sigla TUV

Producător: **B. Braun Avitum AG**
Schwarzenberger Weg 73 – 79
34212 Melsungen
GERMANIA

Unităţi: B. Braun Avitum AG
Schwarzenberger Weg 73 - 79, 34212 Melsungen, GERMANIA

B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11, 41037 Mirandola (MO), ITALIA

B. Braun Medical Kft Production Division
Deli-Kulhater ut2-4, 3200 Gyongyos, UNGARIA

B. BRAUN Vietnam Co, Ltd.
Complexul industrial Thanh Oai, districtul Thanh Oai, 156800 Hanoi,
VIETNAM

Categorie (ii) Produse: Kit pentru dializă şi hemo(dia)filtrare (circuit extracorporal şi dializor)
Linii pentru dializă şi hemo(dia)filtrare

Organismul de certificare al TUV Product Service GmbH declara ca producătorul mai sus menţionat a implementat un sistem de asigurare a calităţii pentru producţie în conformitate cu Anexa II din Directiva privind Dispozitivele medicale. Acest sistem de asigurare a calităţii este in conformitate cu cerinţele prezentei directive si este supus unei supravegheri periodice. Pentru punerea pe piaţă a dispozitivelor din clasa III, este obligatoriu un certificat suplimentar Anexa II (4). A se vedea, de asemenea, notele de pe verso.

Raport nr. 713053585
Valabil de la: 23.06.2015
Valabil până la: 22.06.2020

Data, 18.12.2014
/semnătură indescifrabilă/
Hans-Heiner Junker

Sigla TUV

TUV Product Service GmbH este un Organism Certificat cu număr de identificare 0123.

Subsemnata, **VALERICA PĂTRU**, interpret si traducător autorizat pentru limbile ENGLEZĂ, FRANCEZĂ şi ITALIANĂ în temeiul autorizaţiei nr. 17602, eliberată de Ministerul Justiţiei din România, certific exactitatea traducerii efectuate din limba *ENGLEZĂ* în limba *ROMÂNĂ*, că textul prezentat spre traducere a fost tradus în întregime, fără omisiuni, şi că, prin traducere, înscrisului nu i-au fost denaturate conţinutul şi sensul.

Traducător şi interpret autorizat,
Valerica Pătru (17602)

Ministerul Justiției
VALERICA PĂTRU
Traducător-interpret autorizat
Engleză, Franceză, Italiană
Autorizația nr. 17602

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 16 06 66097 071

Holder of Certificate: **B. Braun Avitum AG**
Schwarzenberger Weg 73-79
34212 Melsungen
GERMANY

Facility(ies):
B. Braun Avitum AG
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY

B. Braun Avitum AG
Am Buschberg 1, 34212 Melsungen, GERMANY

B. Braun Avitum AG, Werk Glandorf
Kattenvenner Straße 32, 49219 Glandorf, GERMANY

Certification Mark:

Scope of Certificate:
Design and Development, Production, Distribution and Servicing of Active and Non-Active Medical Devices for Extracorporeal Blood Treatment (Hemodialysis, Acute Dialysis, Apheresis);
Design and Development, Production and Distribution of Non-Active Medical Devices in various Therapies;
Distribution and Servicing of Active Medical Devices for Reverse Osmosis Systems, Central Concentrate Supply, Ring Piping and Hot Rinse Disinfection Systems

Applied Standard(s):
EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713078602
Valid from: 2016-08-01
Valid until: 2019-07-31

Date, 2016-07-27

Stefan Preiß

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

DAkkS CRT2 / 10.13

Wir

B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germany

erklären in eigener Verantwortung,
dass das/die Produkt/e
Kit für Dialyse und Haemo(dia)filtration
(Artikelnummern siehe Anlage I)
mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen:

Richtlinie 93/42/EWG des Rates vom
14. Juni 1993 über Medizinprodukte

Konformitätsbewertungsverfahren:
nach Anhang II mit Ausnahme der nummer (4)
der oben genannten Richtlinie
Klassifizierung
gemäß Anhang IX der oben genannten Richtlinie:
Klasse IIb, Regel 3
EG-Zertifikat Nr.
G1 14 12 66097 065

Konformitätsbewertungsverfahren:
nach Anhang V und Anhang VII
der oben genannten Richtlinie
Klassifizierung
gemäß Anhang IX der oben genannten Richtlinie:
Klasse I Sterile, Regel 1
EG-Zertifikat Nr.
G2S 17 08 66097 082
Benannte Stelle:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 München, Deutschland
Kennnummer 0123

Datum der ersten CE-Kennzeichnung:
2015-01

Doc #: 02/15-RA-fo
Doc Rev #: 4.0
Rev date: 2017-12-14

Gültigkeit dieser Erklärung:
von 2018-01-10
bis 2020-06-22

Glandorf,

Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

We

B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germany

hereby declare in our own responsibility
that the product/s
Kit for Dialysis and Haemo(dia)filtration
(article numbers see attachment I)
is/are in compliance with the following directive:

Council Directive 93/42/EEC of 14 June 1993
concerning medical devices

Conformity assessment procedure:
according to annex II excluding (4)
of the Directive named above
Classification
according to annex IX of the Directive named above:
Class IIb, Rule 3
EC Certificate No.
G1 14 12 66097 065

Conformity assessment procedure:
according to Annex V and Annex VII
of the Directive named above
Classification
according to annex IX of the Directive named above:
Class I Sterile, Rule 1
EC Certificate No.
G2S 17 08 66097 082
Notified body:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich, Germany
Identification number 0123

Date of first CE-marking:
2015-01

Doc #: 02/15-RA-fo
Doc Rev #: 4.0
Rev date: 2017-12-14

Validity of this declaration:
from 2018-01-10
until 2020-06-22

Mirandola, 2017.12.14

Dr. Giuliana Gavioli
Head of Division RA

Anlage I / Attachment I

Art. No.	Description	Class	Rule
7211136	OMNIset Including 0.8 sqm Hemofilter	IIb	3
7211137	OMNIset Including 1.2 sqm Hemofilter	IIb	3
7211151	OMNIset Including 1.6 sqm Hemofilter	IIb	3
7211065	OMNIbag 7000 mL Effluent bag	I sterile	1

Glandorf,

Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

Mirandola, 2017-12-19

Dr. Giuliana Gavioli
Head of Division RA

Best Trados
birou de traduceri

Str. Paul Chinezu nr. 4, Timisoara, Romania
E-mail: office@besttrados.ro
Tel.: +40 722 555 883

Traducere din limba engleză

B BRAUN

Declarație de Conformitate
(FORMULAR)

B. Braun Avitum
{B. Braun Avitum Italia S.p.A.}
ID formular: SOP-MBC574
Versiune: A

Subscrisa
B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germania
Declarăm prin prezenta pe propria răspundere că produsul/ele
Kit pentru Dializă şi Hemo (dia) filtrare
(numerele articolelor se găsesc în anexa I)
este/sunt in conformitate cu urmatoarea directiva
Directiva Consiliului 93/42/CEE din 14 iunie 1993 cu privire la Dispozitivele medicale

Procedura de Evaluare a Conformitatii
conform anexei II (excluzând secţiunea 4)
a Directivei de mai sus

Clasificare
conform anexei IX la Directiva amintită mai sus,
Clasa IIb, Regulament 3

Nr. certificat CE
G1 14 12 66097 065

Procedura de Evaluare a Conformitatii
conform anexei V şi Anexei VII
a Directivei de mai sus

Clasificare
conform anexei IX la Directiva amintită mai sus,
Clasa I Sterile, Regulament 1

Nr. certificat CE
G2S 12 10 66097 048

Agenţie Notificată
TUV SUD Product Service GmbH
Ridlerstrasse 65
80339 Munchen
Germania
Număr identificare 0123

Data primului marcaj CE
01-2015
Doc #: 02/15-RA-fo
Doc Rev #: 3.0
Data revizuirii: 30.03.2017

B BRAUN

Declarație de Conformitate
(FORMULAR)

B. Braun Avitum
{B. Braun Avitum Italia S.p.A.}
ID formular: SOP-MBC574
Versiune: A

Anexa I

Nr. art.	Descriere articol	Clasa	Regulament
7211136	OMNIset Including 0.8 sqm Hemofilter	IIb	3
7211137	OMNIset Including 1.2 sqm Hemofilter	IIb	3
7211151	OMNIset Including 1.6 sqm Hemofilter	IIb	3
7211065	OMNIbag 7000 mL Effluent bag	I sterile	1

Subsemnata, **VALERICA PĂTRU**, interpret si traducător autorizat pentru limbile ENGLEZĂ, FRANCEZĂ şi ITALIANĂ în temeiul autorizaţiei nr. 17602, eliberată de Ministerul Justiţiei din România, certific exactitatea traducerii efectuate din limba ***ENGLEZĂ*** în limba ***ROMÂNĂ***, că textul prezentat spre traducere a fost tradus în întregime, fără omisiuni, şi că, prin traducere, înscrisului nu i-au fost denaturate conţinutul şi sensul.

Traducător şi interpret autorizat,
Valerica Pătru (17602)

Ministerul Justiției
VALERICA PĂTRU
Traducător interpret autorizat
Engleză, franceză, italiană
Autorizația nr. 17602

Valabilitatea acestei declaraţii:
de la 04.04.2017
până la 09.01.2018

Glandorf, 04.04.2017
Anton Deisser
Director Fluide, concentrate şi instrumente de unică folosinţă CoE
-semnătură indescifrabilă-

Mirandola, 30.03.2017
Dr. Giuliana Gavioli
Director Divizie RA
-semnătură indescifrabilă-

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 17 11 66097 086

Manufacturer:

B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
GERMANY

Facility(ies):

B. Braun Avitum AG, Werk Glandorf
Kattenvenner Straße 32, 49219 Glandorf, GERMANY

B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11, 41037 Mirandola (MO), ITALY

Product Category(ies):

Sterile and non-sterile hemodialysis concentrates (class IIb), solid dosage form for hemodialysis (class IIb), and irrigation solutions (class IIa)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713120020

Valid from: 2018-02-17
Valid until: 2023-02-16

Date, 2017-11-29

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

A1 / 04.11

ERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Traducere din limba engleză

CERTIFICAT CE
SISTEMUL COMPLET DE ASIGURARE A CALITATII

(Directiva 93/42/CEE privind Dispozitivele medicale), Anexa II excluzând (4)
(Dispozitive in clasa IIa, IIb sau III)
Număr G1 17 11 66097 086

Sigla TUV

Producător: **B. Braun Avitum AG**
Schwarzenberger Weg 73 – 79
34212 Melsungen
GERMANIA

Unități: **B. Braun Avitum AG, Werk Glandorf Kattenvenner Strasse 32, 49219 Glandorf, GERMANIA**

B. Braun Avitum Italia S.p.A.
Via XXV Luglio, 11, 41037 Mirandola (MO), ITALIA

Categorie (ii) Produse: Concentrate de hemodializă sterile şi nesterile (clasa IIb), formă solidă de dozare pentru hemodializă (clasa IIb) şi soluţii de irigare (clasa IIa)

Organismul de certificare al TUV Product Service GmbH declară ca producătorul mai sus menţionat a implementat un sistem de asigurare a calităţii pentru producţie în conformitate cu Anexa II din Directiva privind Dispozitivele medicale. Acest sistem de asigurare a calităţii este in conformitate cu cerinţele prezentei directive si este supus unei supravegheri periodice. Pentru punerea pe piaţă a dispozitivelor din clasa III, este obligatoriu un certificat suplimentar Anexa II (4). A se vedea, de asemenea, notele de pe verso.

Raport nr. 713120020
Valabil de la: 17.02.2018
Valabil până la: 16.02.2023

Data, 29.11.2017
/semnătură indescifrabilă/
Stefan Preiss

Sigla TUV

TUV Product Service GmbH este un Organism Certificat cu număr de identificare 0123.

Subsemnata, **VALERICA PĂTRU**, interpret si traducător autorizat pentru limbile ENGLEZĂ, FRANCEZĂ şi ITALIANĂ în temeiul autorizaţiei nr. 17602, eliberată de Ministerul Justiţiei din România, certific exactitatea traducerii efectuate din limba *ENGLEZĂ* în limba *ROMÂNĂ,* că textul prezentat spre traducere a fost tradus în întregime, fără omisiuni, şi că, prin traducere, înscrisului nu i-au fost denaturate conţinutul şi sensul.

Traducător şi interpret autorizat,
Valerica Pătru (17602)

Ministerul Justiției
VALERICA PĂTRU
Traducător interpret autorizat
Engleză, Franceză, Italiană
Autorizația nr. 17602

Wir | We

B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germany

erklären in eigener Verantwortung, dass das/die Produkt/e

Sterile Bicarbonatlösungen für Hämodialyse
(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie übereinstimmt/übereinstimmen:

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte

Konformitätsbewertungsverfahren:
nach Anhang II mit Ausnahme der nummer (4) der oben genannten Richtlinie

Klassifizierung
gemäß Anhang IX der oben genannten Richtlinie:
Klasse IIb, Regel 3

EG-Zertifikat Nr.
G1 17 10 66097 086

Benannte Stelle:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 München, Deutschland
Kennnummer 0123

Datum der ersten CE-Kennzeichnung:
2015-06

Doc #: 94/15-RA-fo
Doc Rev #: 2.0
Rev date: 2018-01-22

Gültigkeit dieser Erklärung:
von 2018-02-17
bis 2023-02-16

hereby declare in our own responsibility that the product/s

Sterile Bicarbonate Solutions for Haemodialysis
(article numbers see attachment I)

is/are in compliance with the following directive:

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Conformity assessment procedure:
according to annex II excluding (4) of the Directive named above

Classification
according to annex IX of the Directive named above:
Class IIb, Rule 3

EC Certificate No.
G1 17 10 66097 086

Notified body:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich, Germany
Identification number 0123

Date of first CE-marking:
2015-06

Doc #: 94/15-RA-fo
Doc Rev #: 2.0
Rev date: 2018-01-22

Validity of this declaration:
from 2018-02-17
until 2023-02-16

Radeberg, 24.01.2018

Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

Mirandola, 22/01/2018

Dr. Giuliana Gavioli
Head of Division RA

Anlage I / Attachment I

Art.-Nr. / Art. No.	Artikelbezeichnung / Article description	Klasse / Class	Regel / Rule
8972	Sterile Bicarbonate solution without Potassium for haemodialysis	IIb	3
8973	Sterile Bicarbonate solution with 2 mmol/l Potassium for haemodialysis	IIb	3
8974	Sterile Bicarbonate solution with 4 mmol/l Potassium for haemodialysis	IIb	3

Radeberg, 24.01.2018

Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

Mirandola, 22/01/2018

Dr. Giuliana Gavioli
Head of Division RA