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 according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50565-Z5-00, the decision dated 2018-10-04 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-11-30 to 2023-11-29

Registration No.: 50565-16-06

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-10-04
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

84460

Annex to the EC Certificate No. 50565-16-06

Valid from 2018-11-30 to 2023-11-29

Revision status of the annex: 1 dated 2019-05-20

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
  - Connector LT

Class III:

MD 0203

- Dialysis Catheter PU-LT
  - Kits
  - Catheter
- Dialysis Catheter Silicone 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.

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 • DEKRA DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-05-20
Notified Body ID-number: 0124

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 according to the Directive 93/42/EEC Annex V for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50565-Z5-00, the decision dated 2018-10-04 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-11-30 to 2023-11-29

Registration No.: 50565-17-05

DEKRA Certification GmbH • DEKRA Certification • D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-10-04
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

84460

Annex to the EC Certificate No. 50565-17-05

Valid from 2018-11-30 to 2023-11-29

Revision status of the annex: 0 dated 2018-11-30

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

- Miniclamp

MD 0106

- Mixer

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2018-10-04
Notified Body ID-number: 0124

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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 Str. 50
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 directive 93/42/EEC

allen Anforderungen der 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

gemäß Richtlinie 93/42/EWG, Anhang II ohne Abschnitt (4) /
according to directive 93/42/EEC Annex II without section (4)

Konformitätsbewertungsstelle / Notified Body

DEKRA Certification GmbH
Handwerkstr. 15
70565 Stuttgart
Germany
ID: 0124

Diese Erklärung ist gültig bis zum 29.11.2023 bzw. bis zur Ausstellung einer revidierten Erklärung. /
This declaration is valid until 2023-11-29 or until a revised declaration comes into effect.

Hechingen, 2018-11-30

Michael Eisenlohr
Site Manager

Dr. Marian Wenzel
Director QA/RA

Joline®

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

ANHANG – PRODUKTLISTE / ANNEX – PRODUCT LIST

Single Lumen Short Term

DCPT 8/10	DCPT 8/17,5 PH	PKSL08P150C	PKSL08P250
DCPT 8/15	DCPT 8/20 H-PH	PKSL08P175	PKSL08P250C
DCPT 8/15 H-PH	DCPT 8/20 PH	PKSL08P175C	
DCPT 8/15 PH	DCPT 8/25 PH	PKSL08P200	
DCPT 8/17,5 H-PH	PKSL08P150	PKSL08P200C	

Single Lumen ST (Händler / Distributor)

-PKSL08P150	-PKSL08P175	-PKSL08P200	-PKSL08P250

Double Lumen Short Term Extra Flow Kits

HF-DLS 11/12,5	KEF11P100	KEF11P250R	PKHF11P175
HF-DLS 11/12,5 C	KEF11P125	KEF11P300	PKHF11P200
HF-DLS 11/15	KEF11P125C	KEF11P300C	PKHF11P250
HF-DLS 11/15 C	KEF11P125R	KEF11P300R	PKHF11P150R
HF-DLS 11/15 C 14	KEF11P150	KEF11PH125R	PKHF11P175R
HF-DLS 11/17,5	KEF11P150C	KEF11PH150C	PKHF11P125
HF-DLS 11/17,5 C	KEF11P150R	KEF11PH150R	PKHF11P225
HF-DLS 11/20	KEF11P175	KEF11PH175	PKHF11P125R
HF-DLS 11/20 C	KEF11P175C	KEF11PH175R	PKHF11P200R
HF-DLS 11/20 C 14	KEF11P175R	KEF11PH200	PKHF11P225R
HF-DLS 11/22,5	KEF11P200	KEF11PH200C	PKHF11P250R
HF-DLS 11/25	KEF11P200C	KEF11PH200R	PKHF11P150R 21
HF-DLS 11/25 C	KEF11P200R	KEF11PH250	PKHF11P150C 21
HF-DLS 11/25 C 14	KEF11P225R	KEF11PH300	PKHF11P175C 21
HF-DLS 11/30	KEF11P250	PKHF11P150	

Double Lumen ST Extra Flow (Händler / Distributor)

-PKHF11P150	-PKHF11P200	-PKHF11P150R	-PKHF11P200R
-PKHF11P175	-PKHF11P250	-PKHF11P175R	-PKHF11P250R

Double Lumen Short Term Standard - Einzelkatheter und Kits

DLS 11/20 C	KDL11P150R	KDL11PH125C	PKDL11P150 21
DLS 11/12,5	KDL11P175	KDL11PH125R	PKDL11P150C 21
DLS 11/15	KDL11P175C	KDL11PH150	PKDL11P150R
DLS 11/15 C	KDL11P175R	KDL11PH150C	PKDL11P175
DLS 11/17,5	KDL11P200	KDL11PH150R	PKDL11P175 21
DLS 11/17,5 C	KDL11P200C	KDL11PH175	PKDL11P175C 21
DLS 11/20	KDL11P200R	KDL11PH175C	PKDL11P175R
DLS 11/25	KDL11P225	KDL11PH175R	PKDL11P200
KDL11P100	KDL11P225C	KDL11PH200	PKDL11P200R
KDL11P100C	KDL11P225R	KDL11PH200C	PKDL11P250
KDL11P125	KDL11P250	KDL11PH200R	PKDL11P250R
KDL11P125C	KDL11P250C	KDL11PH250	PKDL11PH200
KDL11P125R	KDL11P250R	PKDL11P125	
KDL11P150	KDL11PH100R	PKDL11P125R	
KDL11P150C	KDL11PH125	PKDL11P150	

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Double Lumen ST (Händler / Distributor)

-PKDL11P125	-PKDL11P200	-PKDL11P150R	-PKDL11P250R
-PKDL11P150	-PKDL11P250	-PKDL11P175R	
-PKDL11P175	-PKDL11P125R	-PKDL11P200R	

Double Lumen Short Term High Flow Kits

HF-DLS 13/15	HF-DLS 13/20 C	PKHF13PH150C 21	PKHF13PH200R
HF-DLS 13/15 C	HF-DLS 13/25	PKHF13PH150R	PKHF13PH250
HF-DLS 13/17,5	HF-DLS 13/22,5	PKHF13PH175	PKHF13PH250R
HF-DLS 13/17,5 C	PKHF13PH150	PKHF13PH175R	PKHF13PH300
HF-DLS 13/20	PKHF13PH150 21	PKHF13PH200	

High Flow Double Lumen ST (Händler / Distributor)

-PKHF13PH150	-PKHF13PH200	-PKHF13PH150R	-PKHF13PH200R
-PKHF13PH175	-PKHF13PH250	-PKHF13PH175R	-PKHF13PH250R

Double Lumen Extra Flow - Pädiatrisch

KDL06P075	KDL08P075C	P-DLS 6,5/7,5	PKDL06P125R
KDL06P075C	KDL08P075R	P-DLS 6,5/7,5 C	PKDL08P075 21
KDL06P075R	KDL08P100	P-DLS 8/15	PKDL08P100
KDL06P100	KDL08P100C	P-DLS 8/10 C	PKDL08P100R
KDL06P100C	KDL08P100R	P-DLS 8/12,5	PKDL08P125
KDL06P100R	KDL08P125	P-DLS 8/12,5 C	PKDL08P125R
KDL06P125	KDL08P125C	P-DLS 8/7,5	PKDL08P150
KDL06P125C	KDL08P125R	P-DLS 8/10	PKDL08P150 21
KDL06P125R	KDL08P150	PKDL06P075	PKDL08P150R
KDL06P150	KDL08P150C	PKDL06P075R	
KDL06P150C	KDL08P150R	PKDL06P100	
KDL06P150R	P-DLS 6,5/10	PKDL06P100R	
KDL08P075	P-DLS 6,5/10 C	PKDL06P125	

Extra Flow Double Lumen (Händler / Distributor)

-PKDL08P100	-PKDL08P100R	-PKDL06P075	-PKDL06P075R
-PKDL08P125	-PKDL08P125R	-PKDL06P100	-PKDL06P100R
-PKDL08P150	-PKDL08P150R	-PKDL06P125	-PKDL06P125R

Triple Lumen Short Term

KTL12P125	KTL12P175R	PKTL12P150 C 21	PKTL12P200C 21
KTL12P125R	KTL12P200	PKTL12P150R	PKTL12P200 21
KTL12P150	KTL12P200C	PKTL12P175	PKTL12P200R
KTL12P150C	KTL12P200R	PKTL12P175 21	PKTL12P250R
KTL12P150R	KTL12P225	PKTL12P175C 21	PKTL12P250
KTL12P175	KTL12P250	PKTL12P175R	
KTL12P175C	PKTL12P150	PKTL12P200	

Triple Lumen ST Händler

-PKTL12P150	-PKTL12P200	-PKTL12P150R	-PKTL12P200R
-PKTL12P175	-PKTL12P250	-PKTL12P175R	-PKTL12P250R

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Triple Lumen Short Term High Flow

HF-TLK 13/15	HF-TLK 13/25	PKTHF13P150R	PKTHF13P200R
HF-TLK 13/15 C	HF-TLK 13/30	PKTHF13P175	PKTHF13P250
HF-TLK 13/17,5	HF-TLK 13/30 C	PKTHF13P175R	PKTHF13P250R
HF-TLK 13/17,5 C	PKTHF13P150	PKTHF13P175C 21	
HF-TLK 13/20	PKTHF13P150 21	PKTHF13P200	
HF-TLK 13/20 C	PKTHF13P150 C 21	PKTHF13P200 21	

Triple Lumen ST Händler

-PKTHF13P150	-PKTHF13P200	-PKTHF13P150R	-PKTHF13P200R
-PKTHF13P175	-PKTHF13P250	-PKTHF13P175R	-PKTHF13P250R

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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 according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50565-Z5-00, the decision dated 2018-10-04 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-11-30 to 2023-11-29

Registration No.: 50565-16-06

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-10-04
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

84460

Annex to the EC Certificate No. 50565-16-06

Valid from 2018-11-30 to 2023-11-29

Revision status of the annex: 1 dated 2019-05-20

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
  - Connector LT

Class III:

MD 0203

- Dialysis Catheter PU-LT
  - Kits
  - Catheter
- Dialysis Catheter Silicone 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.

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 • DEKRA DEKRA Certification

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-05-20
Notified Body ID-number: 0124

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 according to the Directive 93/42/EEC Annex V for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50565-Z5-00, the decision dated 2018-10-04 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2018-11-30 to 2023-11-29

Registration No.: 50565-17-05

DEKRA Certification GmbH • DEKRA Certification • D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-10-04
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

84460

Annex to the EC Certificate No. 50565-17-05

Valid from 2018-11-30 to 2023-11-29

Revision status of the annex: 0 dated 2018-11-30

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

- Miniclamp

MD 0106

- Mixer

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2018-10-04
Notified Body ID-number: 0124

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 Str. 50
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 directive 93/42/EEC

allen Anforderungen der 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

gemäß Richtlinie 93/42/EWG, Anhang II ohne Abschnitt (4) /
according to directive 93/42/EEC Annex II without section (4)

Konformitätsbewertungsstelle / Notified Body

DEKRA Certification GmbH
Handwerkstr. 15
70565 Stuttgart
Germany
ID: 0124

Diese Erklärung ist gültig bis zum 29.11.2023 bzw. bis zur Ausstellung einer revidierten Erklärung. /
This declaration is valid until 2023-11-29 or until a revised declaration comes into effect.

Hechingen, 2018-11-30

Michael Eisenlohr
Site Manager

Dr. Marian Wenzel
Director QA/RA

Joline®

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

ANHANG – PRODUKTLISTE / ANNEX – PRODUCT LIST

Single Lumen Short Term

DCPT 8/10	DCPT 8/17,5 PH	PKSL08P150C	PKSL08P250
DCPT 8/15	DCPT 8/20 H-PH	PKSL08P175	PKSL08P250C
DCPT 8/15 H-PH	DCPT 8/20 PH	PKSL08P175C	
DCPT 8/15 PH	DCPT 8/25 PH	PKSL08P200	
DCPT 8/17,5 H-PH	PKSL08P150	PKSL08P200C	

Single Lumen ST (Händler / Distributor)

-PKSL08P150	-PKSL08P175	-PKSL08P200	-PKSL08P250

Double Lumen Short Term Extra Flow Kits

HF-DLS 11/12,5	KEF11P100	KEF11P250R	PKHF11P175
HF-DLS 11/12,5 C	KEF11P125	KEF11P300	PKHF11P200
HF-DLS 11/15	KEF11P125C	KEF11P300C	PKHF11P250
HF-DLS 11/15 C	KEF11P125R	KEF11P300R	PKHF11P150R
HF-DLS 11/15 C 14	KEF11P150	KEF11PH125R	PKHF11P175R
HF-DLS 11/17,5	KEF11P150C	KEF11PH150C	PKHF11P125
HF-DLS 11/17,5 C	KEF11P150R	KEF11PH150R	PKHF11P225
HF-DLS 11/20	KEF11P175	KEF11PH175	PKHF11P125R
HF-DLS 11/20 C	KEF11P175C	KEF11PH175R	PKHF11P200R
HF-DLS 11/20 C 14	KEF11P175R	KEF11PH200	PKHF11P225R
HF-DLS 11/22,5	KEF11P200	KEF11PH200C	PKHF11P250R
HF-DLS 11/25	KEF11P200C	KEF11PH200R	PKHF11P150R 21
HF-DLS 11/25 C	KEF11P200R	KEF11PH250	PKHF11P150C 21
HF-DLS 11/25 C 14	KEF11P225R	KEF11PH300	PKHF11P175C 21
HF-DLS 11/30	KEF11P250	PKHF11P150	

Double Lumen ST Extra Flow (Händler / Distributor)

-PKHF11P150	-PKHF11P200	-PKHF11P150R	-PKHF11P200R
-PKHF11P175	-PKHF11P250	-PKHF11P175R	-PKHF11P250R

Double Lumen Short Term Standard - Einzelkatheter und Kits

DLS 11/20 C	KDL11P150R	KDL11PH125C	PKDL11P150 21
DLS 11/12,5	KDL11P175	KDL11PH125R	PKDL11P150C 21
DLS 11/15	KDL11P175C	KDL11PH150	PKDL11P150R
DLS 11/15 C	KDL11P175R	KDL11PH150C	PKDL11P175
DLS 11/17,5	KDL11P200	KDL11PH150R	PKDL11P175 21
DLS 11/17,5 C	KDL11P200C	KDL11PH175	PKDL11P175C 21
DLS 11/20	KDL11P200R	KDL11PH175C	PKDL11P175R
DLS 11/25	KDL11P225	KDL11PH175R	PKDL11P200
KDL11P100	KDL11P225C	KDL11PH200	PKDL11P200R
KDL11P100C	KDL11P225R	KDL11PH200C	PKDL11P250
KDL11P125	KDL11P250	KDL11PH200R	PKDL11P250R
KDL11P125C	KDL11P250C	KDL11PH250	PKDL11PH200
KDL11P125R	KDL11P250R	PKDL11P125	
KDL11P150	KDL11PH100R	PKDL11P125R	
KDL11P150C	KDL11PH125	PKDL11P150	

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Double Lumen ST (Händler / Distributor)

-PKDL11P125	-PKDL11P200	-PKDL11P150R	-PKDL11P250R
-PKDL11P150	-PKDL11P250	-PKDL11P175R	
-PKDL11P175	-PKDL11P125R	-PKDL11P200R	

Double Lumen Short Term High Flow Kits

HF-DLS 13/15	HF-DLS 13/20 C	PKHF13PH150C 21	PKHF13PH200R
HF-DLS 13/15 C	HF-DLS 13/25	PKHF13PH150R	PKHF13PH250
HF-DLS 13/17,5	HF-DLS 13/22,5	PKHF13PH175	PKHF13PH250R
HF-DLS 13/17,5 C	PKHF13PH150	PKHF13PH175R	PKHF13PH300
HF-DLS 13/20	PKHF13PH150 21	PKHF13PH200	

High Flow Double Lumen ST (Händler / Distributor)

-PKHF13PH150	-PKHF13PH200	-PKHF13PH150R	-PKHF13PH200R
-PKHF13PH175	-PKHF13PH250	-PKHF13PH175R	-PKHF13PH250R

Double Lumen Extra Flow - Pädiatrisch

KDL06P075	KDL08P075C	P-DLS 6,5/7,5	PKDL06P125R
KDL06P075C	KDL08P075R	P-DLS 6,5/7,5 C	PKDL08P075 21
KDL06P075R	KDL08P100	P-DLS 8/15	PKDL08P100
KDL06P100	KDL08P100C	P-DLS 8/10 C	PKDL08P100R
KDL06P100C	KDL08P100R	P-DLS 8/12,5	PKDL08P125
KDL06P100R	KDL08P125	P-DLS 8/12,5 C	PKDL08P125R
KDL06P125	KDL08P125C	P-DLS 8/7,5	PKDL08P150
KDL06P125C	KDL08P125R	P-DLS 8/10	PKDL08P150 21
KDL06P125R	KDL08P150	PKDL06P075	PKDL08P150R
KDL06P150	KDL08P150C	PKDL06P075R	
KDL06P150C	KDL08P150R	PKDL06P100	
KDL06P150R	P-DLS 6,5/10	PKDL06P100R	
KDL08P075	P-DLS 6,5/10 C	PKDL06P125	

Extra Flow Double Lumen (Händler / Distributor)

-PKDL08P100	-PKDL08P100R	-PKDL06P075	-PKDL06P075R
-PKDL08P125	-PKDL08P125R	-PKDL06P100	-PKDL06P100R
-PKDL08P150	-PKDL08P150R	-PKDL06P125	-PKDL06P125R

Triple Lumen Short Term

KTL12P125	KTL12P175R	PKTL12P150 C 21	PKTL12P200C 21
KTL12P125R	KTL12P200	PKTL12P150R	PKTL12P200 21
KTL12P150	KTL12P200C	PKTL12P175	PKTL12P200R
KTL12P150C	KTL12P200R	PKTL12P175 21	PKTL12P250R
KTL12P150R	KTL12P225	PKTL12P175C 21	PKTL12P250
KTL12P175	KTL12P250	PKTL12P175R	
KTL12P175C	PKTL12P150	PKTL12P200	

Triple Lumen ST Händler

-PKTL12P150	-PKTL12P200	-PKTL12P150R	-PKTL12P200R
-PKTL12P175	-PKTL12P250	-PKTL12P175R	-PKTL12P250R

R14

Joline®

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

Triple Lumen Short Term High Flow

HF-TLK 13/15	HF-TLK 13/25	PKTHF13P150R	PKTHF13P200R
HF-TLK 13/15 C	HF-TLK 13/30	PKTHF13P175	PKTHF13P250
HF-TLK 13/17,5	HF-TLK 13/30 C	PKTHF13P175R	PKTHF13P250R
HF-TLK 13/17,5 C	PKTHF13P150	PKTHF13P175C 21	
HF-TLK 13/20	PKTHF13P150 21	PKTHF13P200	
HF-TLK 13/20 C	PKTHF13P150 C 21	PKTHF13P200 21	

Triple Lumen ST Händler

-PKTHF13P150	-PKTHF13P200	-PKTHF13P150R	-PKTHF13P200R
-PKTHF13P175	-PKTHF13P250	-PKTHF13P175R	-PKTHF13P250R

R14

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: 26 May 2024
Issued for the first time: 25 March 2011
Reissued: 22 July 2019

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
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-product-safety.com Company registration 09085396

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
- P2Y12 Inhibitor-Ticagrelor Removal
- Rivaroxaban Removal

Initial date: 25 March 2011
Revision date: 8 April 2020

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.A. van Vugt
Certification Manager

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

CERTIFICAT CE

Numărul: 3804606CE01

Sistem complet de asigurare a calității

Directiva 93/42/CEE privind dispozitivele medicale, anexa II, cu excepția (4)
(Dispozitive 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 de produse

Sisteme de adsorbție pe bază de polimeri

DEKRA acordă dreptul de a utiliza numărul de identificare al organismului notificat CE ilustrat mai jos pentru a însoți marcajul CE de conformitate pe produsele în cauză conform cu documentația tehnică necesară și respectând dispozițiile directivei CE care li se aplică:

0344

Documente care stau la baza acestui certificat:
Aviz de certificare 3804606CN, datată inițial la 20 septembrie 2010 Act adițional, datat inițial 25 martie 2011

Prin prezenta, DEKRA declară că producătorul menționat mai sus îndeplinește dispozițiile relevante ale „Besluit Medische Hulpmiddelen", transpunerea olandeză a Directivei 93/42/CEE a Consiliului din 14 iunie 1993 privind dispozitivele medicale, cu modificările ulterioare. Producătorul a pus în aplicare un sistem de asigurare a calității pentru proiectarea, fabricarea și inspecția finală a categoriei de produse menționată mai sus, în conformitate cu dispozițiile din anexa II la Directiva 93/42/CEE a Consiliului din 14 iunie 1993 și este supus supravegherii periodice. Pentru introducerea pe piață a dispozitivelor de clasa a III-a este obligatoriu un certificat suplimentar de examinare CE de proiect conform anexei II (4).
Informațiile necesare referitoare la sistemul de management al calității al producătorului, inclusiv facilitățile și trimiterea la documentația relevantă, a produselor în cauză și evaluările efectuate, sunt menționate în avizul de certificare care face parte integrantă din acest certificat.

Acest certificat este valabil până la: 26 mai 2024
Eliberat pentru prima dată la: 25 martie 2011
Republicat la: 22 iulie 2019

DEKRA Certification B.V.

MINISTERUL JUSTIȚIEI
SESOVICI LAURA
Traducător Aut.
Aut. nr. 17538/23.10.2009
CONSTANȚA - ROMÂNIA

B.T.M. Holtus //semnătură indescifrabilă
Director General

J.A. van Vugt //semnătură indescifrabilă
Manager Certificări

DEKRA Certification BV este un organism notificat cu 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-product-safety.com Număr de înregistrare 09085396

ACT ADIȚIONAL

La certificatul: 3804606CE01 **1/1**

MARCAJ DE CONFORMITATE CE
DISPOZITIVE MEDICALE

Sisteme de adsorbție pe bază de polimeri

Emis către:

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

Acest certificat acoperă următoarele produse:

- Adsorbție de citokină, bilirubină și mioglobină
- Îndepărtarea inhibitorilor Ticagrelor P2Y12
- Eliminarea Rivaroxaban

Data inițială: 25 martie 2011
Data revizuirii: 8 aprilie 2020

MINISTERUL JUSTIȚIEI SESOVICI LAURA Traducător Aut. Aut. nr. 17538/23.10.2006 CONSTANȚA - ROMÂNIA

DEKRA Certification B.V.

B.T.M. Holtus
//semnătură indescifrabilă
Director General

J.A. van Vugt //semnătură indescifrabilă
Manager Certificări

DEKRA Certification BV este un organism notificat cu 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-product-safety.com Număr de înregistrare 09085396

CytoSorbents

Seven Deer Park Drive, Suite K
Monmouth Junction, NJ 08852
Tel 732.329.8885
Fax 732.329.8650

Declarație de conformitate
Sisteme de adsorbție pe bază de polimeri

CytoSorbents Inc. are responsabilitatea exclusivă asupra conformității produselor marcate CE distribuite, specificate în lista de produse anexată, cu cerințele normative aplicabile, acoperite de:

Certificat de Conformitate CE **Certificat nr. 3804606CE01**	
Descriere	**Data**
Prima certificare	25 martie 2011
Reînnoire	1 septembrie 2013
Reînnoire	1 septembrie 2016
Reînnoire	22 iulie 2019

Emis de DEKRA Certification BV, Organism notificat cu nr. de identificare 0344, conform cu Anexa II la Directiva CE, Directiva Consiliului 93/42/CEE din 14 iunie 1993 privind dispozitivele medicale.

În plus, asigurăm și declarăm că produsele marcate CE distribuite, așa cum sunt menționate și încadrate în Clasa IIb conform cu Anexa IX, norma 3[1], întrunesc prevederile Directivei CE care li se aplică.

Prezenta declarație se bazează pe aplicarea sistemului de calitate aprobat pentru proiectarea, producția și inspecția finală a produselor vizate, în concordanță cu Anexa II la Directiva CE. Conformitatea sistemului complet de asigurare a calității stabilit în Anexa II este descrisă în Certificatul de conformitate CE emis și comunicat de DEKRA Certification BV.

[1] Norma 3 – toate dispozitivele neinvazive concepute pentru modificarea compoziției biologice sau chimice a sângelui, altor fluide corporale sau altor lichide destinate infuzării în organism sunt încadrate în Clasa IIb, dacă tratamentul nu constă din filtrarea, centrifugarea sau schimbul de gaze, căldură, caz în care sunt încadrate în Clasa IIa.

CytoSorbents

Seven Deer Park Drive, Suite K
Monmouth Junction, NJ 08852
Tel 732.329.8885
Fax 732.329.8650

Prezenta declarație de conformitate acoperă sistemele de adsorbție pe bază de polimeri specificate în lista de produse atașată la această declarație și este valabilă pentru toate produsele vizate care poartă marcajul CE și sunt fabricate în următoarele unități:

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

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

Reprezentant autorizat în CE:

MedPass SAS
95 bis Boulevard Pereire
75017 Paris
Franța

[semnătură indescifrabilă] [ștampila rotundă CytoSorbents Inc.] 19 august 2019
Matthew J. Gilliland Data
Director, Calitate/Sisteme de Calitate

Anexă: Lista de produse

- Dispozitiv CytoSorb 300 ml

CytoSorbents

Seven Deer Park Drive, Suite K
Monmouth Junction, NJ 08852
P 732.329.8885
F 732.329.8650
www.cytosorbents.com

Declaration of Conformity
Polymer Based Adsorption Systems

CytoSorbents Inc. has the sole responsibility that the distributed CE marked products, specified in the annexed product list, conform to the applicable regulatory requirements covered by:

CE Marking of Conformity Certificate Certificate #3804606CE01	
Description	**Date**
Initial Certification	March 25, 2011
Renewal	September 01, 2013
Renewal	September 01, 2016
Renewal	July 22, 2019

Delivered by DEKRA Certification B.V., 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 according to Annex IX, Rule 3[1] , 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 B.V.

[1] Rule 3 – All non-invasive devices intended for modifying the biological or chemical composition of blood, other body fluids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIa.

CytoSorbents

Seven Deer Park Drive, Suite K
Monmouth Junction, NJ 08852
P 732.329.8885
F 732.329.8650
www.cytosorbents.com

This Declaration of Conform 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 sites:

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

CytoSorbents Inc.
11 Deer Park Drive
Suite 125
Monmouth Junction, NJ 08852
United States of America

Retaining the EC Authorized Representative:

MedPass SAS
95 bis Boulevard Pereire
75017 Paris
France

Matthew J. Gilliland
Director, Quality/Quality Systems

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

19 AUG 2019
Date

Annex: Product List

- CytoSorb 300mL Device

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-

Wir

We

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 066097 0096 Rev. 02

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 #: 11.0
Rev date: 2020-03-04

Gültigkeit dieser Erklärung:
von 2020-03-09
bis 2023-01-09

Radeberg, 2020/03/09

Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

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 066097 0096 Rev. 02

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 #: 11.0
Rev date: 2020-03-04

Validity of this declaration:
from 2020-03-09
until 2023-01-09

Mirandola, 09.03.20

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
7211265	OMNIset Plus Including 1.6 sqm Hemofilter	IIb	3
7211427	OMNIset® Plus	IIb	3
7211432	OMNIset® ECCO$_2$R	IIb	3
7211287	OMNIset PRO Including 1.3 sqm Hemofilter	IIb	3
7211288	OMNIset PRO Including 1.6 sqm Hemofilter	IIb	3
7211367	OMNIset® L 1.6 m²	IIb	3
7211368	OMNIset® 0.8 m²	IIb	3
7211369	OMNIset® 1.2 m²	IIb	3
7211370	OMNIset® 1.6 m²	IIb	3
7211371	OMNIset® Pro 0.8 m²	IIb	3
7211372	OMNIset® Pro 1.2 m²	IIb	3
7211373	OMNIset® Pro 1.6 m²	IIb	3
7211422	OMNIset® 1.3 m²	IIb	3
7211423	OMNIset® 1.6 m²	IIb	3
7211428	OMNIset® 1.3 m²	IIb	3
7211429	OMNIset® 1.6 m²	IIb	3
7211425	OMNIset® Pro 1.3 m²	IIb	3
7211426	OMNIset® Pro 1.6 m²	IIb	3
7211376	OMNIset® Pro 1.3m²	IIb	3
7211377	OMNIset® Pro 1.6 m²	IIb	3
7211065	OMNIbag 7000 mL Effluent bag	I sterile	1

Radeberg, 2020/03/09

Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

Mirandola, 10.03.05

Dr. Giuliana Gavioli
Head of Division RA

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

TÜV®

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 ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 066097 0096 Rev. 02

Manufacturer:

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

Product Category(ies):

Active and non-active medical devices for extracorporeal blood treatments:
- Active medical devices for extracorporeal blood treatment: hemodialysis, acute dialysis, plasmapheresis.
Reverse osmosis Systems, central concentrate supply Systems, ring piping and hot disinfection Systems for dialysis;
- Kit for Dialysis and Haemo(dia)filtration (extracorporeal Circuit and dialyser); Lines for Dialysis and Haemo(dia)filtration;
- Kit for Plasma Treatment (Extracorporeal Circuit and Plasma filter); Lines for Plasma Treatment;
-Dialyzers, hemofilters, hemodiafilters, dialysis fluid filters, hemofilters for continuous renal replacement therapy;
- Plasma Filter Haemoselect;
- Blood filtration devices; H.E.L.P. SYSTEM kit;
- S.A.F.E. Apheresis Set;
- A.V. Fistula needles
- Catheters and Catheter Sets for Dialysis;
- Disinfectants for Dialysis Machines;
- 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.: 713168200

Valid from: 2020-02-28
Valid until: 2024-05-26

Date, 2020-02-28

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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A4 / 07.17

Wir

We

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 066097 0096 Rev. 02

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 #: 11.0
Rev date: 2020-03-04

Gültigkeit dieser Erklärung:
von 2020-03-09
bis 2023-01-09

Radeberg, 2020/03/09

Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

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 066097 0096 Rev. 02

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 #: 11.0
Rev date: 2020-03-04

Validity of this declaration:
from 2020-03-09
until 2023-01-09

Mirandola, 09.03.20

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
7211265	OMNIset Plus Including 1.6 sqm Hemofilter	IIb	3
7211427	OMNIset® Plus	IIb	3
7211432	OMNIset® ECCO$_2$R	IIb	3
7211287	OMNIset PRO Including 1.3 sqm Hemofilter	IIb	3
7211288	OMNIset PRO Including 1.6 sqm Hemofilter	IIb	3
7211367	OMNIset® L 1.6 m²	IIb	3
7211368	OMNIset® 0.8 m²	IIb	3
7211369	OMNIset® 1.2 m²	IIb	3
7211370	OMNIset® 1.6 m²	IIb	3
7211371	OMNIset® Pro 0.8 m²	IIb	3
7211372	OMNIset® Pro 1.2 m²	IIb	3
7211373	OMNIset® Pro 1.6 m²	IIb	3
7211422	OMNIset® 1.3 m²	IIb	3
7211423	OMNIset® 1.6 m²	IIb	3
7211428	OMNIset® 1.3 m²	IIb	3
7211429	OMNIset® 1.6 m²	IIb	3
7211425	OMNIset® Pro 1.3 m²	IIb	3
7211426	OMNIset® Pro 1.6 m²	IIb	3
7211376	OMNIset® Pro 1.3m²	IIb	3
7211377	OMNIset® Pro 1.6 m²	IIb	3
7211065	OMNIbag 7000 mL Effluent bag	I sterile	1

Radeberg, 2020/03/09

Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

Mirandola, 10.03.05

Dr. Giuliana Gavioli
Head of Division RA

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

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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

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DAkkS CRT2 / 10.13

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

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

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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