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

Digitally signed by Ceaicovschi Tudor
Date: 2024.01.30 08:40:01 EET
Reason: MoldSign Signature
Location: Moldova

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

Product Service

Confirmation Statement related to the EC Certificate (MDD)

List of Sites involved in the Product Realisation Processes

No. GDS 066097 0103 Rev. 00

Manufacturer:

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

This List of Sites is only valid in combination with the following EC Certificate (MDD): **G1 066097 0096 Rev. 02**

The following pages list all sites under the manufacturer's quality system where product realisation processes are conducted for those devices covered by the aforementioned EC Certificate pursuant to the Directive 93/42/EEC (MDD) concerning medical devices.

Report No.: 713168200

Valid until: 2024-05-26

Issue Date: 2020-02-28

MÜNCHEN TÜV SÜD PRODUCT SERVICE

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Product Service

Confirmation Statement related to the EC Certificate (MDD)

List of Sites involved in the Product Realisation Processes

No. GDS 066097 0103 Rev. 00

Sites:

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

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

B. Braun Avitum Saxonia GmbH
Juri-Gagarin-Strasse 13, 01454 Radeberg, GERMANY

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

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

B. Braun Melsungen AG
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

Lauer Membran Wassertechnik GmbH
Speichermatt 9, 79599 Wittlingen, GERMANY

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

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 066097 0082 Rev. 01

Manufacturer	**B. Braun Avitum AG** Schwarzenberger Weg 73-79 34212 Melsungen GERMANY
Product Category(ies):	**Accessories for dialysis, infusion and apheresis (class I sterile)** **Rinsing and priming solutions (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.: 713168203

Valid from: 2020-05-13
Valid until: 2024-05-26

Date, 2020-05-13

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

TÜV®

Wir

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

erklären in eigener Verantwortung,
dass das/die Produkt/e
Kit für Plasmabehandlung
(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 IIa, 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 066097 0082 Rev. 01
Benannte Stelle:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 München, Deutschland
Kennnummer 0123

Datum der ersten CE-Kennzeichnung:
2017-07

Doc #: 78/17-RA-fo
Doc Rev #: 7.0
Rev date: 2020-05-25

Gültigkeit dieser Erklärung:
von 2020-05-28
bis 2024-05-26

Mirandola, 2021-05-18

Francesco Benatti
Head of CoE Renal & WOC Consumables

We

hereby declare in our own responsibility
that the product/s
Kit for Plasma Treatment
(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 IIa, 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 066097 0082 Rev. 01
Notified body:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich, Germany
Identification number 0123

Date of first CE-marking:
2017-07

Doc #: 78/17-RA-fo
Doc Rev #: 7.0
Rev date: 2020-05-25

Validity of this declaration:
from 2020-05-28
until 2024-05-26

Mirandola, 2021-05-18

Chiara Bergamini
Head of Division RA

Anlage I / Attachment I

Art. No.	Description	Class	Rule
7211153	OMNIset® TPE 0.5 m^2	IIa	3
7211154	OMNIset® TPE 0.7 m^2	IIa	3
7211467	OMNIset® TPE 0.5 m^2	IIa	3
7211468	OMNIset® TPE 0.7 m^2	IIa	3
7211065	OMNIbag 7000 mL Effluent bag	I sterile	1

Mirandola, 2021-05-18

Francesco Benatti
Head of CoE Renal & WOC Consumables

Mirandola, 2021-05-18

Chiara Bergamini
Head of Division RA

Subscrisa

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

declară prin prezenta pe propria răspundere că produsul

Kit pentru tratament cu plasmă
(pentru numerele articolelor consultați anexa I)

este în conformitate cu următoarea directivă:

Directiva Consiliului 93/42/CEE din 14 iunie 1993 cu privire la dispozitivele medicale

Procedura de evaluare a conformității:
conform Anexei II cu excepția secțiunii 4 din Directiva menționată anterior

Clasificare
în conformitate cu Anexa IX din Directiva menționată anterior: Clasa IIb, Regula 3

Nr. Certificat CE
G1 066097 0096 Rev. 02

Procedura de evaluare a conformității:
conform Anexei V și Anexei VII din Directiva menționată anterior

Clasificare
în conformitare cu Anexa IX din Directiva menționată anterior: Clasa I Sterile, Regula 1

Nr. Certificat CE
G2S 066097 0082 Rev. 01

Organism notificat:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 München, Germania
Număr de identificare 0123

Data primului marcaj CE:
2017-07

Doc #: 78/17-RA-fo
Rev. Doc #: 7.0
Data rev.: 25-05-2020

Valabilitatea acestei declarații:
De la 28-05-2020
Până la 26-05-2024

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

Mirandola, 18.05.2021
Semnătură indescifrabilă
Francesco Benatti
Șef al Fluide, Concentrați și Consumabile CoE

Mirandola, 18.05.2021
Semnătură indescifrabilă
Chiara Bergamini
Șef al Diviziei RA

Anexa I

Nr. Art.	Descriere	Clasa	Regula
7211153	OMNIset® TPE 0,5 m^2	IIa	3
7211154	OMNIset® TPE 0,7 m^2	IIa	3
7211467	OMNIset® TPE 0,5 m^2	IIa	3
7211468	OMNIset® TPE 0,7 m^2	IIa	3
7211065	OMNIbag 7000 mL pungă de efluenți	I steril	1

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

Mirandola, 18.05.2021
Semnătură indescifrabilă
Francesco Benatti
Șef al Fluide, Concentrați și Consumabile CoE

Mirandola, 18.05.2021
Semnătură indescifrabilă
Chiara Bergamini
Șef al Diviziei RA

DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

Joline GmbH & Co. KG
Mr. Dr. Marian Wenzel
Neue Rottenburger Str. 50
72379 Hechingen
Germany

DEKRA Certification GmbH
Handwerkstraße 15
D-70565 Stuttgart

Contact Stephanie Donner
Phone -
Fax +49.711.7861-2615
Email stephanie.donner@dekra.com

Headquarters
Phone +49.711.7861-2566
Fax +49.711.7861-2615

Date 2023-11-29

Subject: Notified Body Confirmation Letter

Our reference: 50565-CoL-01, Rev.0

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Dr. Wenzel,

This letter confirms that, DEKRA Certification GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0124 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Joline GmbH & Co. KG
Neue Rottenburger Str. 50
72379 Hechingen
Deutschland

SRN Number: DE-MF-000005494

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables 1 and 2 below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive MDD. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive MDD.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the

date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments) >

On behalf of the Notified Body,

Stephanie Donner
2023-11-29

Digitally signed by Stephanie Donner
Date: 2023-11-29 15:41:00+01:00

Enclosures:

Confirmation Letter Annex

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Product or product group identification acc. to MDD - certificate	MDD Device classification	MDD Certificate and Certificate Annex No. with revision	MDR Application ID
MD 0106 **Kyphoplasty Systems ALLEVO** - **Kits** - **Individual Instruments**	Class IIa	Certificate 50565-16-06 Annex Rev. 2	A22051293
MD 0102 **Dialysis Catheter ST** - **Kits** - **Catheter**	Class IIa	Certificate 50565-16-06 Annex Rev. 2	A22071097
MD 0203 **Dialysis Catheter PU-LT** - **Kits** - **Catheter**	Class III	Certificate 50565-16-06 Annex Rev. 2	A22071097
MD 0203 **Dialysis Catheter Silicone LT** - **Kits** - **Catheter**	Class III	Certificate 50565-16-06 Annex Rev. 2	A22071097
MD0101 **Miniclamp**	Class Is	Certificate 50565-17-05 Annex Rev. 0	A22051293
MD 0106 **Mixer**	Class Is	Certificate 50565-17-05 Annex Rev. 0	A21091017

Joline®

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

Manufacturer's Declaration

Manufacturer name	Joline GmbH & Co. KG
Manufacturer address and contact details	Neue Rottenburger Str. 50 72379 Hechingen Germany
Single Registration Number (SRN)	DE-MF-000005494

Notified body name	DEKRA Certification GmbH
Notified body number	0124
Directive Certificate number(s) to which this confirmation is made	see attached schedule of devices
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	see attached schedule of devices
End date of extended validity/transition period	see attached schedule of devices

In relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 (MDR) as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

we, as the manufacturer, declare under our sole responsibility for the affected listed **Directive Certificates** (see attached schedule), the **listed device(s) in the attached schedule of devices** that we as their manufacturer are in compliance with the conditions listed in Article 120(3c) of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

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

➢ **Directive Certificate(s)** as listed above or in the attached schedule

Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards. They expire *after* 20 March 2023:

We have made formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment to our notified body no later than 26 May 2024 for the devices listed in the attached schedule. Signed written agreements with our notified body will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

A QMS in accordance with Article 10(9) MDR is in place.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

JOLINE GmbH & Co. KG
Neue Rottenburger Str. 50
72379 Hechingen
Germany
Phone: +49 (0) 7471 9881-0
Fax: +49 (0) 7471 9881-111

Hechingen, 2023-11-06

.....

i.A. Dr. Marian Wenzel
Director QA/RA, Person Responsible for Regulatory Compliance
Joline GmbH & Co. KG

Joline®

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

Schedule of Devices

The Manufacturer's Declaration above is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)**
Kyphoplasty Systems ALLEVO • Kits • Individual Instruments	50565-16-06	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2028-12-31**	N/A
Dialysis Catheter ST • Kits • Catheter	50565-16-06	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2028-12-31**	N/A
Dialysis Catheter PU-LT • Kits • Catheter	50565-16-06	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2027-12-31**	N/A
Dialysis Catheter Silicone LT • Kits • Catheter	50565-16-06	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2027-12-31**	N/A
Dialysis Accessories: • Introducer needle	50565-16-06	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2028-12-31**	N/A
Dialysis Accessories: • Dilator	50565-16-06	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2028-12-31**	N/A
Dialysis Accessories: • Connector LT	50565-16-06	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2028-12-31**	N/A
Miniclamp	50565-17-05	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2028-12-31**	N/A
Mixer	50565-17-05	**2023-11-29**	DEKRA Certification GmbH, ID 0124	DEKRA Certification GmbH, ID 0124	**2028-12-31**	N/A

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

Product Service

Certificat CE

Sistem complet de asigurare a calității
Directiva 93/42/CEE privind dispozitivele medicale (MDD), Anexa V
(Dispozitive din Clasa I în condiții sterile, sisteme sterilizate sau pachete pentru proceduri)
Nr. G2S 066097 0082 Rev. 01

Producător:	**B. Braun Avitum AG** Schwarzenberger Weg 73-79 34212 Melsungen GERMANIA
Categorii de produs:	**Accesorii pentru dializă, infuzii și afereză (clasa I steril)** **Soluții de clătire și de preimunizare** **(clasa I steril)**

Organul de Certificare al TUV SUD Product Service GmbH declară că producătorul de mai sus a implementat un sistem de asigurare a calității pentru producție în conformitate cu Anexa V la Directiva Dispozitivelor Medicale. Acest sistem de asigurare a calității acoperă acele aspecte ale producției pentru asigurarea și menținerea condițiilor sterile ale dispozitivelor/categoriilor de dispozitive respective și respectă cerințele acestei Directive. Se supune supravegherii periodice. Vezi și notele de pe verso.

Nr. raportului:	713168203
Valabil de la:	13.05.2020
Valabil până la:	26.05.2024

Data, 13.05.2020

Christoph Dicks
Directorul Organului de Certificare/Notificat
Semnătură indescifrabilă

TUV SUD Product Service GmbH este Organ Notificat cu nr. de identificare 0123
TUV SUD Product Service GmbH Organ de Certificare Ridlerstraße 65 80339 Munchen Germania

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

Subscrisa

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

declară pe propria răspundere că produsul/produsele

Soluții sterile de bicarbonat pentru hemodializă

(pentru numerele de articol, a se vedea anexa I)

este/sunt în conformitate cu următoarea directivă:

Directiva 93/42/CEE a Consiliului din 14 iunie 1993 privind dispozitivele medicale

Procedura de evaluare a conformității:
în conformitate cu anexa II, cu excepția alineatului (4) din directiva menționată anterior

Clasificare
în conformitate cu anexa IX la directiva menționată mai sus:
Clasa IIb, regula 3

Certificat CE nr.
G1 066097 0096 Rev. 02

Organism notificat:
TUV SUD Product Service GmbH RidlerstraBe 65, 80339 München, Germania Număr de identificare 0123

Data primei marcări CE:
2015-06

Nr. doc. 94/15-RA-fo
Doc Rev #: 4.0
Data de revizuire: 02.03.2020

Valabilitatea prezentei declarații:
de la 09.03.2020
până la 26.05.2024

Radeberg, 09.03.2020
//semnat

Anton Deisser
Director CoE Fluide, concentrate și produse de unică folosință

Mirandola, 05.03.2020
//semnat

Dr. Giuliana Gavioli
Șef de divizie RA

Anexa I

Art. Nr.	Descrierea articolului	Clasa	Regula
8972	Soluție sterilă de bicarbonat fără potasiu pentru hemodializă	IIb	3
8973	Soluție sterilă de bicarbonat cu 2 mmol/l Potasiu pentru hemodializă	IIb	3
8974	Soluție sterilă de bicarbonat cu 4 mmol/l Potasiu pentru hemodializă	IIb	3

Radeberg, 09.03.2020
//semnat

Anton Deisser
Director CoE Fluide, concentrate și produse de unică folosință

Mirandola, 05.03.2020
//semnat

Dr. Giuliana Gavioli
Șef de divizie RA

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 066097 0096 Rev. 02

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 #: 4.0
Rev date: 2020-03-02

Gültigkeit dieser Erklärung:
von 2020-03-09
bis 2024-05-26

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 066097 0096 Rev. 02

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 #: 4.0
Rev date: 2020-03-02

Validity of this declaration:
from 2020-03-09
until 2024-05-26

Radeberg, 2020/03/09

Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

Mirandola, 2020-03-05

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, 2020/03/09

Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

Mirandola, 2020-03-05

Dr. Giuliana Gavioli
Head of Division RA

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

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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

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

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
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