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: 2023.02.13 09:19:39 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

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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

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

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®

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

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 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

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

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
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

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

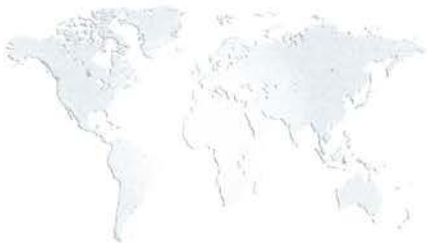
For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

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

CERTIFICAT CE
pentru Sistemul de Asigurare a Calității

conform Directivei 93/42/CEE,
Anexa II, cu excepția secțiunii (4)

În calitate de organism notificat al Uniunii Europene, DEKRA Certification GmbH certifică că societatea
Joline GmbH & Co. KG
Str. Neue Rottenburger, nr. 50, 72379 Hechingen, Germania

implementează un sistem de asigurare a calității conform Directivei 93/42/CEE, Anexa II pentru dispozitivele medicale enumerate în anexă. Aprobarea se bazează pe rezultatul raportului de audit de certificare nr. 50565-Z5-00, hotărârii din 2018-10-04 și este valabilă doar în legătură cu îndeplinirea cu succes a auditorilor de supraveghere anuale.

Prezentul certificat este valabil de la 2018-11-30 la 2023-11-29.

Nr. de înregistrare: 50565-16-06

[semnătură indescifrabilă]
Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-10-24
Număr organism notificat: 0124

MIHAELA BALCĂ

Anexa la certificatul CE nr. 50565-16-06

Valabilă de la 2018-11-30 la 2023-11-29
Stadiul reviziei anexei: 0 din 2018-11-30
Dispozitive / categoriile dispozitivelor incluse în certificat:

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

MD 0106
- Sisteme de chifoplastie ALLEVO
  - Kituri
  - Instrumente individuale

- Accesorii pentru dializă
  - Ac introductor
  - Fir de ghidaj
  - Dilatator
  - Trocar
  - Conector LT
- Cateter de extracție de pietre

Clasa III:
MD 0203
- Cateter dializă PU-LT
  - Kituri
  - Cateter

- Cateter dializă din silicon LT
  - Kituri
  - Cateter

MD 0106
- Forceps biopsie KNIPSA

Pentru introducerea pe piață a dispozitivelor din clasa III acoperite de prezentul certificat, este necesară întocmirea unui certificat CE de examinare conform Directivei 93/42/CEE, Anexa II (4).

[semnătură indescifrabilă]
Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2018-10-24
Număr organism notificat: 0124

DEKRA Certification GmbH * Str. Handwerk, nr. 15 * D-70565 Stuttgart * www.dekra-certification.de

CERTIFICAT CE

pentru sistemul de asigurare a calității

în conformitate cu Directiva 93142 / CEE), anexa V

În calitate de organism notificat al Uniunii Europene, DEKRA Certification Gmbh certifică faptul că firma

Joline GmbH & Co. KG

Neue Rottenburger Straße 50/712319 Hechingen, Germania

aplică un sistem de asigurare a calității conform Directivei 93/42 / CEE anexa V pentru dispozitivele medicale enumerate în anexă. Aprobarea se bazează pe rezultatul raportului de audit de re-certificare nr. 50565-Z5-00, decizia din 2018-10-04 și este valabilă numai în legătură cu efectuarea cu succes a auditurilor anuale de supraveghere.

Acest certificat este valabil din 2018-11-30 până în 2023-11-29

Număr de înregistrare: 50565-17-05

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

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

MIHAELA BALTĂ

ANEXA LA CERTIFICATUL NR. 50565-17-05

Valabil din 2018-11-30 până în 2023-11-29

Statutul revizuirii anexei: 0 din 2018-11-30

Dispozitive / Categorii de dispozitive incluse în certificat:

Clasa I:

Pentru produsele enumerate mai jos, revizuirea sistemului de asigurare a calității se referă exclusiv la aspectele de fabricație referitoare la asigurarea și menținerea condițiilor sterile.

MD 0101

- Miniclemă

MD 0106

- Mixer

MIHAELA BALTĂ

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	

R14

Joline®

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

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

JOLINE GmbH & Co KG. Neva Rottenburger Str. 50.0-72379 Hechingen

DECLARAŢIE DE CONFORMITATE

Numele și adresa firmei
Joline GmbH & Co. KG
Neue Rottenburger Str. 50
72379 Hechingen
Germania

Declarăm pe propria răspundere că dispozitivul medical

Cateter dializă ST în conformitate cu anexa

de clasa IIa conform anexei IX la Directiva 93/42 / CEE

îndeplinește toate dispozițiile Directivei 93/42 / CEE care se aplică acesteia.

Procedura de evaluare a conformității

conform Directivei 93/42 / CEE Anexa II fără secțiunea (4)

Organism notificat

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

Această declarație este valabilă până în 2023-11-29 sau până la intrarea în vigoare a unei declarații revizuite.

Hechingen, 2018-11-30

Michael Eisenlohr
Site Manager

Dr. Marian Wenzel
Director QA/RA

TRADUCĂTOR AUTORIZAT DE MINISTERUL JUSTIȚIEI
MIHAELA BALTĂ
Aut. Nr. 9839
ROMÂNIA

JOLINE GmbH & Co KG. Neva Rottenburger Str. 50.0-72379 Hechingen

ANEXĂ - LISTĂ PRODUSE

Termen scurt un singur lumen

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	

Un singur lumen ST

-PKSL08P150	-PKSL08P175	-PKSL08P200	-PKSL08P250

Kituri termen scurt lumen dublu extra debit

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	

Lumen dublu ST extra debit

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

Lumen dublu termen scurt standard

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	

TRADUCĂTOR AUTORIZAT DE MINISTERUL JUSTIȚIEI MIHAELA BALTĂ Aut. Nr. 0830 ROMÂNIA

JOLINE GmbH & Co KG. Neva Rottenburger Str. 50.0-72379 Hechingen

Lumen dublu ST

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

Kituri lumen dublu termen scurt debit ridicat

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	

Debit ridicat lumen dublu ST

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

Lumen dublu extra debit

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 debit lumen dublu

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

Lumen triplu termen scurt

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	

Lumen triplu ST

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

R14

Lumen triplu termen scurt debit ridicat

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	

Lumen triplu ST

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

R14

EC COMPLIANCE DECLARATION

No. MDT/1

As per Act no. 22/1997 Sb. on technical requirements for products as amended and as per Government Decree no. 54/2015 Sb. which governs technical requirements for medical devices as amended and in harmony with the requirements of the Council Directive 93/42/EEC for medical devices

Manufacturer: **MEDITES PHARMA, spol. s r. o.**
Registered office: **Rožnov pod Radhoštěm, 1. máje 2625, Czech Republic CZ - 756 61**
Company registration number: **45194815**

hereby declares that the sterile medical devices

CITRASOL

which types are listed in the appendix "A", which is an inseparable part of this declaration,

meets essential requirements defined in attachment 1 to the Government Decree number 54/2015 Sb. and the Council Directive 93/42/EEC which requirements apply to it with regard to the intended use.

Description of the medical device:

The medical device CITRASOL 4% (Natrii citras 4%) is supplied in PP bags with a volume of 250 ml (filled volume 250 ml), 1 000 ml (filled volume 1 000 ml) and 2 000 ml (filled volume 1 500 ml and 2 000 ml). The bags are closed with 2 connectors and packed individually in a wrapping bag.

The medical device CITRASOL 0,5% (Natrii citras 0,5 %) is supplied in 5 000 ml PP bag (filled volume 5 000 ml). The bags are closed with 2 connectors and packed individually in a wrapping bag.

The medical device CITRASOL ACD-A is supplied in PP bags with a volume of 250 ml (filled volume 250 ml), 500 ml (filled volume 500 ml) and 1 000 ml (filled volume 750 ml). The bags are closed with 2 connectors and packed into a wrapping bag.

The medical device CITRASOL CPD50 is supplied in PP bags with a volume of 250 ml (filled volume 150 ml and 250 ml). The bags are closed with 2 connectors and packed into a wrapping bag.

The medical device is sterile, clear, and free of bacterial endotoxines.

Intended use:
The medical devices CITRASOL 4% and CITRASOL 0,5% are used as anticoagulant during continuous elimination methods (Continuous Renal Replacement Therapy-CRRT).
The medical device CITRASOL 4% is also intended for aphaeresis procedures and sorptive methods.

The medical devices CITRASOL ACD-A and CITRASOL CPD50 are solutions intended for anticoagulation of whole blood during automated apheresis.

Grade as per the attachment no. 9 of the Government Decree 54/2015 Sb.; classification rule no. 3: IIb
Non-invasive medical device intended for adjusting biological or chemical composition of blood, other bodily fluids, or other fluids intended for intravenous drip.

Following requirements are met during production and distribution:
ČSN EN ISO 13 485 ed. 2: 2016, ČSN EN ISO 14 971:2012, ČSN EN ISO 15223-1:2017, Czech pharmacopoeia and internal regulations of MEDITES PHARMA spol. s r.o.

Following notified body has participated in evaluation of the compliance:
Name: INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI
Registered office: Třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
Number of the notified body: 1023
Company registration number: 47910381

which issued ES Certificate no. 19 0664 QS/NB rev. d (valid from 2021-05-04 to 2024-05-27) as per addendum II 2 of the Council Directive 93/42/EEC.

In Rožnov pod Radhoštěm, dated 4th May 2021

MEDITES PHARMA
spol. s r.o.
756 61 Rožnov pod Radhoštěm

Libuše Franová, executive
name, title and description of the manufacturer's responsible person

Supersedes EC compliance declaration no. MDT/1 dated: 13.10.2020

Appendix "A" to ES compliance declaration, which was issued on 4th May 2021:

Variants medical devices CITRASOL:

	REF
CITRASOL 4% 250 ml	**601030**
CITRASOL 4% 250 ml	**601031**
CITRASOL 4% 1 000 ml	**601010**
CITRASOL 4% 1 000 ml	**601011**
CITRASOL 4% 1 500 ml	**601510**
CITRASOL 4% 2 000 ml	**601023**
CITRASOL 4% 2 000 ml	**601021**
CITRASOL 0,5% 5 000 ml	**603050**
CITRASOL ACD- A 250 ml	**604030**
CITRASOL ACD- A 250 ml	**604031**
CITRASOL ACD- A 500 ml	**604050**
CITRASOL ACD- A 500 ml	**604051**
CITRASOL ACD- A 750 ml	**604080**
CITRASOL ACD- A 750 ml	**604081**
CITRASOL CPD50 150 ml	**605020**
CITRASOL CPD50 150 ml	**605021**
CITRASOL CPD50 250 ml	**605030**
CITRASOL CPD50 250 ml	**605031**

EC COMPLIANCE DECLARATION

no. MDT/3

As per Act no. 22/1997 Sb. on technical requirements for products as amended and as per Government Decree no. 54/2015 Sb. which governs technical requirements for medical devices as amended and in harmony with the requirements of the Council Directive 93/42/EEC for medical devices

Manufacturer: **MEDITES PHARMA, spol. s r. o.**
Registered office: **Rožnov pod Radhoštěm, 1. máje 2625, Czech Republic**
CZ - 756 61
Company registration number: **45194815**

hereby declares that the medical device

MEXSOL

which types are listed in the appendix "A", which is an inseparable part of this declaration,

meets essential requirements defined in attachment 1 to the Government Decree number 54/2015 Sb. and the Council Directive 93/42/EEC which requirements apply to it with regard to the intended use.

Description of the medical device: the medical device is supplied in double chamber PP bags, volume 5 000 ml, closed with 3 connectors. The bags are vacuum packed into a wrapping bag.
The medical device is sterile, clear and free from bacterial endotoxins.

Intended use:
Sterile calcium-free medical devices in variants and with trade names:
MEXSOL K0 Bi15, MEXSOL K0 Bi20, MEXSOL K2 Bi15, MEXSOL K2 Bi20, MEXSOL K4 Bi15, MEXSOL K4 Bi20, MEXSOL K2 Bi20 P0, MEXSOL K4 Bi20 P0, MEXSOL K2 Bi20 P+, MEXSOL K4 Bi20 P+
are used as dialysis solutions for continuous venous to venous haemodialysis (CVVHD) with citrate anticoagulation using 4% sodium citrate solution and simultaneous administration of calcium.

Sterile calcium-free medical devices in variants and with trade names:
MEXSOL G K2 Bi22 a MEXSOL G K4 Bi22
are used as dialysis solutions for continuous venous to venous haemodialysis (CVVHD) and for continuous veno-venous hemodiafiltration (CVVHDF) with citrate anticoagulation of 0.5 % with a solution of sodium citrate and with concurrent administration of calcium.

Sterile medical devices containing calcium in variants and with trade names:
MEXSOL H K0 Bi35/ Bicarbonate H K0 Bi35
MEXSOL H K0 Bi35 Mg+/ Bicarbonate H K0 Bi35 Mg+
MEXSOL H K1 Bi35/ Bicarbonate H K1 Bi35
MEXSOL H K1,5 Bi35/ Bicarbonate H K1,5 Bi35
MEXSOL H K2 Bi35/ Bicarbonate H K2 Bi35
MEXSOL H K2 Bi35 Mg+/ Bicarbonate H K2 Bi35 Mg+
MEXSOL H K4 Bi35/ Bicarbonate H K4 Bi35
MEXSOL H K4 Bi35 Mg+/ Bicarbonate H K4 Bi35 M+
are used as dialysis solutions for treatment by renal replacement therapy (RRT).

Sterile medical devices containing calcium in variants and with trade names:
MEXSOL H K1 L40/ Lactate H K1 L40
MEXSOL H K1,5 L40/ Lactate H K1,5 L40
MEXSOL H K2 L40/ Lactate H K2 L40
MEXSOL H K2 L40 Mg+/ Lactate H K2 L40 Mg+
MEXSOL H K1 L45/ Lactate H K1 L45
MEXSOL H K1,5 L45/ Lactate H K1,5 L45
MEXSOL H K2 L45 / Lactate H K2 L45
are used as dialysis solutions for treatment by renal replacement therapy (RRT).

Grade as per the attachment no. 9 of the Government Decree 54/2015 Sb.;
classification rule no. 3: IIb
Non-invasive medical device intended for adjusting biological or chemical composition of blood, other bodily fluids, or other fluids intended for intravenous drip.

Following requirements are met during production and distribution:
ČSN EN ISO 13 485 ed. 2: 2016, ČSN EN ISO 14 971:2012, ČSN EN ISO 15223-1:2017, Czech pharmacopoeia and internal regulations of MEDITES PHARMA spol. s r.o.

The below mentioned notified body participated in assessment of the compliance:

Name:	INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI
Registered office:	Třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
Number of notified body:	1023
Company registration number:	47910381

which issued ES Certificate no. 19 0664 QS/NB rev. d (valid from 2021-05-04 to 2024-05-27) as per addendum II 2 of the Council Directive 93/42/EEC.

ES Certificated issued for medical devices, which are listed in appendix "A" of this declaration.

In Rožnov pod Radhoštěm, dated 4th May 2021

MEDITES PHARMA
spol. s r.o.
756 61 Rožnov pod Radhoštěm

Libuše Franová, executive
Name, title and signature of the manufacturer's responsible person

Supersedes ES compliance declaration no. MDT/3 dated: 13.10.2020

Appendix "A" to ES compliance declaration, which was issued on 4th May 2021:

Variants and trade names of calcium-free medical devices with the presence of bicarbonate:

Trade name	REF
MEXSOL K0 Bi15	701550
MEXSOL K0 Bi20	702050
MEXSOL K2 Bi15	721550
MEXSOL K2 Bi20	722050
MEXSOL K4 Bi15	741550
MEXSOL K4 Bi20	742050
MEXSOL G K2 Bi22	722250
MEXSOL G K4 Bi22	742250
MEXSOL K2 Bi20 P0	722052
MEXSOL K2 Bi20 P0	722060
MEXSOL K2 Bi20 P0	722061
MEXSOL K4 Bi20 P0	742052
MEXSOL K4 Bi20 P0	742060
MEXSOL K4 Bi20 P0	742061
MEXSOL K2 Bi20 P+	722054
MEXSOL K2 Bi20 P+	722057
MEXSOL K2 Bi20 P+	722059
MEXSOL K4 Bi20 P+	742054
MEXSOL K4 Bi20 P+	742057
MEXSOL K4 Bi20 P+	742059

Variants and trade names of medical devices with the presence of calcium and bicarbonate:

Trade name	REF
MEXSOL H K0 Bi35	703560
MEXSOL H K0 Bi35 Mg+	703561
MEXSOL H K1 Bi35	713560
MEXSOL H K1,5 Bi35	763560
MEXSOL H K2 Bi35	723560
MEXSOL H K2 Bi35 Mg+	723561
MEXSOL H K4 Bi35	743560
MEXSOL H K4 Bi35 Mg+	743561

Trade name	REF
Bicarbonate H K0 Bi35	703570
Bicarbonate H K0 Bi35 Mg+	703571
Bicarbonate H K1 Bi35	713570
Bicarbonate H K1,5 Bi35	763570
Bicarbonate H K2 Bi35	723570
Bicarbonate H K2 Bi35 Mg+	723571
Bicarbonate H K4 Bi35	743570
Bicarbonate H K4 Bi35 Mg+	743571

Variants and trade names of medical devices with the presence of calcium and lactates:

Trade name	REF
MEXSOL H K1 L40	714060
MEXSOL H K1,5 L40	764060
MEXSOL H K2 L40	724060
MEXSOL H K2 L40 Mg+	724061
MEXSOL H K1 L45	714560
MEXSOL H K1,5 L45	764560
MEXSOL H K2 L45	724560

Trade name	REF
Lactate H K1 L40	714070
Lactate H K1,5 L40	764070
Lactate H K2 L40	724070
Lactate H K2 L40 Mg+	724071
Lactate H K1 L45	714570
Lactate H K1,5 L45	764570
Lactate H K2 L45	724570

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Certificate - Full Quality Assurance System
No. 19 0664 QS/NB

The quality system of manufacturer

MEDITES PHARMA, spol. s r.o.

1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

has been certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II excluding (4)

for the following product category(ies):

Sterile hemodialysis solutions

The Notified Body No. 1023 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 subjected to periodical surveillance. For placing on the market of Class III devices covered by this certificate, an EC Design-Examination Certificate according to Annex II (Section 4) is required.

Valid from: 2021-05-04
Valid until: 2024-05-27
First Issued: 2019-12-10
Revision: d

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 6

Date: 2021-05-04

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0664 QS/NB

issued for manufacturer:

MEDITES PHARMA, spol. s r.o.
1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

Product(s):

Name:	**CITRASOL**
Trade name(s):	CITRASOL 4% (Natrii citras 4%) CITRASOL 0.5% (Natrii citras 0.5%) CITRASOL ACD-A CITRASOL CPD50
Model(s):	REF 601030 (CITRASOL 4%, volume 250 ml) REF 601031 (CITRASOL 4%, volume 250 ml) REF 601010 (CITRASOL 4%, volume 1000 ml) REF 601011 (CITRASOL 4%, volume 1000 ml) REF 601510 (CITRASOL 4%, volume 1500 ml) REF 601023 (CITRASOL 4%, volume 2000 ml) REF 601021 (CITRASOL 4%, volume 2000 ml) REF 603050 (CITRASOL 0.5%, volume 5000 ml) REF 604030 (CITRASOL ACD-A, volume 250 ml) REF 604031 (CITRASOL ACD-A, volume 250 ml) REF 604050 (CITRASOL ACD-A, volume 500 ml) REF 604051 (CITRASOL ACD-A volume 500 ml) REF 604080 (CITRASOL ACD-A volume 750 ml) REF 604081 (CITRASOL ACD-A, volume 750 ml)

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 6

Date: 2021-05-04
Revision: d

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0664 QS/NB

issued for manufacturer:

MEDITES PHARMA, spol. s r.o.
1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

REF 605020 (CITRASOL CPD50, volume 150 ml)
REF 605021 (CITRASOL CPD50, volume 150 ml)
REF 605030 (CITRASOL CPD50, volume 250 ml)
REF 605031 (CITRASOL CPD50, volume 250 ml)

Class: IIb
GMDN: 45815

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION 6

Date: 2021-05-04
Revision: d

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0664 QS/NB

issued for manufacturer:

MEDITES PHARMA, spol. s r.o.
1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

Name:	**MEXSOL**
Trade name(s):	MEXSOL
Model(s):	K0 Bi15 (REF 701550, volume 4500+500 ml) K0 Bi20 (REF 702050, volume 4500+500 ml) K2 Bi15 (REF 721550, volume 4500+500 ml) K2 Bi20 (REF 722050 volume 4500+500 ml) K4 Bi15 (REF 741550, volume 4500+500 ml) K4 Bi20 (REF 742050, volume 4500+500 ml) K2 Bi20 P0 (REF 722052 / 722060 / 722061, volume 4500+500 ml) K4 Bi20 P0 (REF 742052 / 742060 / 742061, volume 4500+500 ml) K2 Bi20 P+ (REF 722054 / 7222057 / 722059, volume 4500+500 ml) K4 Bi20 P+ (REF 742054 / 742057 / 742059, volume 4500+500 ml)
Class:	IIb
GMDN:	35849

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 6

Date: 2021-05-04
Revision: d

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0664 QS/NB

issued for manufacturer:

MEDITES PHARMA, spol. s r.o.
1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

Name:	**MEXSOL G**
Trade name(s):	MEXSOL G
Model(s):	K2 Bi22 (REF 722250, volume 4500+500 ml) K4 Bi22 (REF 742250, volume 4500+500 ml)
Class:	IIb
GMDN:	35849

Name:	**Bicarbonate H**
Trade name(s):	Bicarbonate H
Model(s):	K0 Bi35 (REF 703570, volume 4500+500 ml) K0 Bi35 Mg+ (REF 703571, volume 4500+500 ml) K1 Bi35 (REF 713570, volume 4500+500 ml) K1,5 Bi35 (REF 763570, volume 4500+500 ml) K2 Bi35 (REF 723570, volume 4500+500 ml) K2 Bi35 Mg+ (REF 723571, volume 4500+500 ml) K4 Bi35 (REF 743570, volume 4500+500 ml) K4 Bi35 Mg+ (REF 743571, volume 4500+500 ml)
Class:	IIb
GMDN:	35849

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 6

Date: 2021-05-04
Revision: d

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0664 QS/NB

issued for manufacturer:

MEDITES PHARMA, spol. s r.o.
1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

Name:	**MEXSOL H**
Trade name(s):	MEXSOL H
Model(s):	K0 Bi35 (REF 703560, volume 4500+500 ml) K0 Bi35 Mg+ (REF 703561, volume 4500+500 ml) K1 Bi35 (REF 713560, volume 4500+500 ml) K1,5 Bi35 (REF 763560, volume 4500+500 ml) K2 Bi35 (REF 723560, volume 4500+500 ml) K2 Bi35 Mg+ (REF 723561, volume 4500+500 ml) K4 Bi35 (REF 743560, volume 4500+500 ml) K4 Bi35 Mg+ (REF 743561, volume 4500+500 ml) K1 L40 (REF 714060, volume 5000 ml) K1,5 L40 (REF 764060, volume 5000 ml) K2 L40 (REF 724060, volume 5000 ml) K2 L40 Mg+ (REF 724061, volume 5000 ml) K1 L45 (REF 714560, volume 5000 ml) K1,5 L45 (REF 764560, volume 5000 ml) K2 L45 (REF 724560, volume 5000 ml)
Class:	IIb
GMDN:	35849

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 6

Date: 2021-05-04
Revision: d

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0664 QS/NB

issued for manufacturer:

MEDITES PHARMA, spol. s r.o.
1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

Name:	**Lactate H**
Trade name(s):	Lactate H
Model(s):	K1 L40 (REF 714070, objem vaku 5000 ml) K1,5 L40 (REF 764070, volume 5000 ml) K2 L40 (REF 724070, volume 5000 ml) K2 L40 Mg+ (REF 724071, volume 5000 ml) K1 L45 (REF 714570, volume 5000 ml) K1,5 L45 (REF 764570, volume 5000 ml) K2 L45 (REF 724570, volume 5000 ml)
Class:	IIb
GMDN:	35849

Name:	**LACSOL**
Trade name(s):	LACSOL
Model(s):	40-107 (REF 541131, volume 5000 ml) 45-100 (REF 541133, volume 5000 ml) 45-101 (REF 541134, volume 5000 ml)
Class:	IIb
GMDN:	35849

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 6

Date: 2021-05-04
Revision: d

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0664 QS/NB

issued for manufacturer:

MEDITES PHARMA, spol. s r.o.
1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

Name:	**BICSOL**
Trade name(s):	BICSOL
Model(s):	35-110 (REF 723550, volume 4500+500 ml) 35-108 K0 (REF 703550, volume 4500+500 ml) 35-112 K4 (REF 743550, volume 4500+500 ml)
Class:	IIb
GMDN:	35849

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 6

Date: 2021-05-04
Revision: d

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0664 QS/NB

issued for manufacturer:

MEDITES PHARMA, spol. s r.o.
1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

Facility(ies):

MEDITES PHARMA, spol. s r.o.
1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

IMUNA PHARM, a.s.
Jarková 269/17, Šarišské Michaľany, Slovak Republic

Haemopharm Biofluids S.r.l.
Via dell'Industria, 6 23030 Tovo di S. Agata (SO), Italy

NOTIFIED BODY 1023 INSTITUTE FOR TESTING AND CERTIFICATION 6

Date: 2021-05-04
Revision: d

Mgr. Jiří Heš
Representative of the Notified Body No. 1023

Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

Annex to EC Certificate No. 19 0664 QS/NB

issued for manufacturer:

MEDITES PHARMA, spol. s r.o.
1. máje 2625, 756 61 Rožnov pod Radhoštěm, Czech Republic

Certificate History:

Revision	Date	Reference Number	Action
	2019-12-10	803602826	Recertification process – conformity assessment of CITRASOL
a	2020-03-17	803602826	Recertification process – conformity assessment of MEXSOL, MEXSOL G, MEXSOL H, Lactate H, Bicarbonate H, LACSOL, BICSOL
b	2020-06-02	803602852	Correction of typing error, products LACSOL and CITRASOL
c	2020-10-13	803602860	Addition of new product models CITRASOL ACD-A and CITRASOL CPD50
d	2021-05-04	803602906	Addition of new product model CITRASOL 4% (REF 601510)

NOTIFIED BODY 1023 · INSTITUTE FOR TESTING AND CERTIFICATION · 6

Date: 2021-05-04
Revision: d

Mgr. Jiří Heš
Representative of the Notified Body No. 1023