



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



Product Service

# EC Certificate

Full Quality Assurance System

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

**No. G1 066097 0096 Rev. 02**

**Manufacturer:**

**B. Braun Avitum AG**

Schwarzenberger Weg 73-79  
34212 Melsungen  
GERMANY

**Product Category(ies):**

**Active and non-active medical devices for extracorporeal blood treatments:**

- Active medical devices for extracorporeal blood treatment: hemodialysis, acute dialysis, plasmapheresis.

Reverse osmosis Systems, central concentrate supply Systems, ring piping and hot disinfection Systems for dialysis;

- Kit for Dialysis and Haemo(dia)filtration (extracorporeal Circuit and dialyser); Lines for Dialysis and Haemo(dia)filtration;

- Kit for Plasma Treatment (Extracorporeal Circuit and Plasma filter); Lines for Plasma Treatment;

-Dialyzers, hemofilters, hemodiafilters, dialysis fluid filters, hemofilters for continuous renal replacement therapy;

- Plasma Filter Haemoselect;

- Blood filtration devices; H.E.L.P. SYSTEM kit;

- S.A.F.E. Apheresis Set;

- A.V. Fistula needles

- Catheters and Catheter Sets for Dialysis;

- Disinfectants for Dialysis Machines;

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

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II.

This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:**

713168200

**Valid from:**

2020-02-28

**Valid until:**

2024-05-26

**Date,**

2020-02-28

Christoph Dicks

Head of Certification/Notified Body



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 **G1 066097 0096 Rev. 02**  
valid in combination with the  
following EC Certificate (MDD):

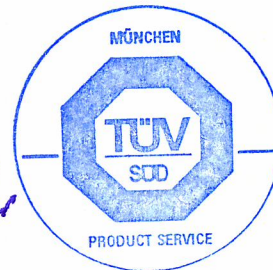
The following pages list all sites under the manufacturer's quality system where product realisation processes are conducted for those devices covered by the aforementioned EC Certificate pursuant to the Directive 93/42/EEC (MDD) concerning medical devices.

**Report No.:** 713168200

**Valid until:** 2024-05-26

**Issue Date:** 2020-02-28

*R. Köhler*





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



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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

**Categoriile 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*

Pagina 1 din 1

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





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 TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD  
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT

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 conformitate 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



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**

<b>Nr. Art.</b>	<b>Descriere</b>	<b>Clasa</b>	<b>Regula</b>
7211153	OMNIsset® TPE 0,5 m <sup>2</sup>	IIa	3
7211154	OMNIsset® TPE 0,7 m <sup>2</sup>	IIa	3
7211467	OMNIsset® TPE 0,5 m <sup>2</sup>	IIa	3
7211468	OMNIsset® TPE 0,7 m <sup>2</sup>	IIa	3
7211065	OMNIbag 7000 mL pungă de efluenți	I steril	1



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

We

**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

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 <sup>2</sup>	Ila	3
7211154	OMNIset® TPE 0.7 m <sup>2</sup>	Ila	3
7211467	OMNIset® TPE 0.5 m <sup>2</sup>	Ila	3
7211468	OMNIset® TPE 0.7 m <sup>2</sup>	Ila	3
7211065	OMNIbag 7000 mL Effluent bag	I sterile	1

Mirandola, *2024-05-18*Francesco Benatti  
Head of CoE Renal & WOC ConsumablesMirandola, *2024-05-18*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  
//semnatMirandola, 05.03.2020  
//semnatAnton Deisser  
Director CoE Fluide, concentrate și produse de unică  
folosințăDr. 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 2024-05-26hereby 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:**

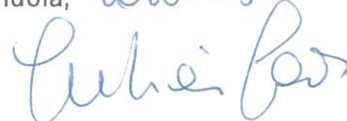
2015-06

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

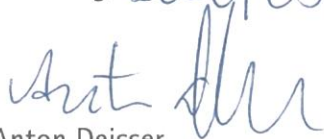
Mirandola, 2020-03-05

Dr. Giuliana Gavioli  
Head of Division RA

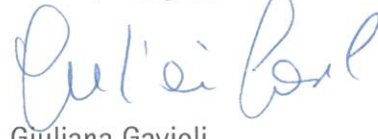
**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Artikelbezeichnung / Article description</b>	<b>Klasse / Class</b>	<b>Regel / Rule</b>
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

## 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:

<b>CE Marking of Conformity Certificate Certificate #3804606CE01</b>	
<b>Description</b>	<b>Date</b>
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<sup>1</sup>, 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.

<sup>1</sup> 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.


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



19 AUG 2019  
Date

## Annex: Product List

- CytoSorb 300mL Device

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**Declarație de conformitate  
Sisteme de adsorbție pe bază de polimeri**

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

<b>Certificat de Conformitate CE</b> <b>Certificat nr. 3804606CE01</b>	
<b>Descriere</b>	<b>Data</b>
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<sup>1</sup>, 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.



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<sup>1</sup> 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, caldura, caz în care sunt încadrate în Clasa IIa.



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.]  
Matthew J. Gilliland  
Director, Calitate/Sisteme de Calitate

19 august 2019  
Data

Anexă: Lista de produse

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- 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

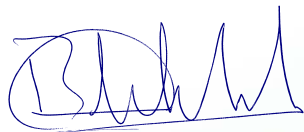
Documents, that form the basis of this certificate:

**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

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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

1/1

## 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**

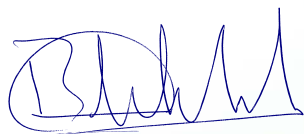
This certificate covers the following product(s):

- 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.

A blue ink signature of B.T.M. Holtus, the Managing Director of DEKRA Certification B.V.

**B.T.M. Holtus**  
Managing Director

A blue ink signature of J.A. van Vugt, the Certification Manager of DEKRA Certification B.V.

**J.A. van Vugt**  
Certification Manager

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# 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 marajul 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, datat 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.

B.T.M. Holtus //semnătură  
indescifrabilă

Director General

J.A. van Vugt //semnătură indescifrabilă

Manager Certificări

© Este permisă publicarea integrală a acestui certificat și a rapoartelor adiacente

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

DEKRA Certification B.V.

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

J.A. van Vugt //semnătură indescifrabilă

Manager Certificări

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# EC CERTIFICATE

## for the Quality Assurance System



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

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

**Joline GmbH & Co. KG**

Neue Rottenburger Straße 50, 72379 Hechingen, Germany

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

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

Registration No.: 50565-16-06



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](http://www.zlg.de)  
**ZLG-BS-295.10.02**

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)

# 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.



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

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)





# 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



A handwritten signature in black ink, appearing to read "Ruth", is written over a horizontal line.



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

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)

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

DEKRA Certification GmbH \* Str. Handwerk, nr. 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)

Pagina 1 din 1



**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](http://www.dekra-certification.de)



# CERTIFICAT CE

pentru sistemul de asigurare a calității



în conformitate cu Directiva 93/42 / 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



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

DEKRA Certification GmbH \* Handwerkstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)



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Medizinprodukten  
www.zlg.de  
ZLG-BS-295.10.02

page 1 of 1



# 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 / Categoriile 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




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

DEKRA Certification GmbH \* Handwerksstraße 15 \* D-70565 Stuttgart \* [www.dekra-certification.de](http://www.dekra-certification.de)





## 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

## 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
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### 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	

## 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



## 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

## DECLARAȚIE 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 Ia conform anexei IX la Directiva 93/42 / CEE

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

### *Procedura de evaluare a conformității*

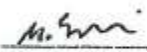
conform Directivei 93/42 / CEE Anexa II fără secțiunea (4)

### *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



## 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
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### 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	



## 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

## Lumen triplu termen scurt debit ridicat

HF-TLK 13/15  
HF-TLK 13/15 C  
HF-TLK 13/17,5  
HF-TLK 13/17,5 C  
HF-TLK 13/20  
HF-TLK 13/20 C

HF-TLK 13/25  
HF-TLK 13/30  
HF-TLK 13/30 C  
PKTHF13P150  
PKTHF13P150 21  
PKTHF13P150 C 21

PKTHF13P150R  
PKTHF13P175  
PKTHF13P175R  
PKTHF13P175C 21  
PKTHF13P200  
PKTHF13P200 21

PKTHF13P200R  
PKTHF13P250  
PKTHF13P250R

## Lumen triplu ST

-PKTHF13P150  
-PKTHF13P175

-PKTHF13P200  
-PKTHF13P250

-PKTHF13P150R  
-PKTHF13P175R

-PKTHF13P200R  
-PKTHF13P250R



## 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 4<sup>th</sup> 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 4<sup>th</sup> May 2021:**

**Variants medical devices CITRASOL:**

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



## 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

### **MXSOL**

**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:  
 MXSOL K0 Bi15, MXSOL K0 Bi20, MXSOL K2 Bi15, MXSOL K2 Bi20, MXSOL K4 Bi15,  
 MXSOL K4 Bi20, MXSOL K2 Bi20 P0, MXSOL K4 Bi20 P0, MXSOL K2 Bi20 P+, MXSOL 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:  
 MXSOL G K2 Bi22 a MXSOL 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:  
 MXSOL H K0 Bi35/ Bicarbonate H K0 Bi35  
 MXSOL H K0 Bi35 Mg+/ Bicarbonate H K0 Bi35 Mg+  
 MXSOL H K1 Bi35/ Bicarbonate H K1 Bi35  
 MXSOL H K1,5 Bi35/ Bicarbonate H K1,5 Bi35  
 MXSOL H K2 Bi35/ Bicarbonate H K2 Bi35  
 MXSOL H K2 Bi35 Mg+/ Bicarbonate H K2 Bi35 Mg+  
 MXSOL H K4 Bi35/ Bicarbonate H K4 Bi35  
 MXSOL 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:  
 MXSOL H K1 L40/ Lactate H K1 L40  
 MXSOL H K1,5 L40/ Lactate H K1,5 L40  
 MXSOL H K2 L40/ Lactate H K2 L40  
 MXSOL H K2 L40 Mg+/ Lactate H K2 L40 Mg+  
 MXSOL H K1 L45/ Lactate H K1 L45  
 MXSOL H K1,5 L45/ Lactate H K1,5 L45  
 MXSOL 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 4<sup>th</sup> 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

**Appendix "A" to ES compliance declaration, which was issued on 4<sup>th</sup> May 2021:**

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

<b>Trade name</b>	<b>REF</b>
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:**

<b>Trade name</b>	<b>REF</b>
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

<b>Trade name</b>	<b>REF</b>
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:**

<b>Trade name</b>	<b>REF</b>
MXSOL H K1 L40	714060
MXSOL H K1,5 L40	764060
MXSOL H K2 L40	724060
MXSOL H K2 L40 Mg+	724061
MXSOL H K1 L45	714560
MXSOL H K1,5 L45	764560
MXSOL H K2 L45	724560

<b>Trade name</b>	<b>REF</b>
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



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)

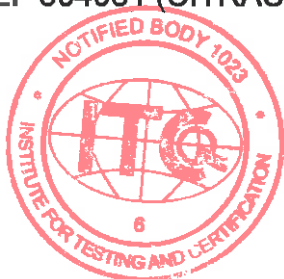
REF 604031 (CITRASOL ACD-A, volume 250 ml)

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)



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:**  
**GMDN:**

**IIb**  
**45815**



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



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**

<b>Name:</b>	<b>MEXSOL G</b>
<b>Trade name(s):</b>	MEXSOL G
<b>Model(s):</b>	K2 Bi22 (REF 722250, volume 4500+500 ml) K4 Bi22 (REF 742250, volume 4500+500 ml)
<b>Class:</b>	IIb
<b>GMDN:</b>	35849
<b>Name:</b>	<b>Bicarbonate H</b>
<b>Trade name(s):</b>	Bicarbonate H
<b>Model(s):</b>	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)
<b>Class:</b>	IIb
<b>GMDN:</b>	35849



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:

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

<b>Name:</b>	<b>MEXSOL H</b>
<b>Trade name(s):</b>	MEXSOL H
<b>Model(s):</b>	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)
<b>Class:</b>	IIb
<b>GMDN:</b>	35849



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**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



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



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**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



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### 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)



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