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

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 066097 0106 Rev. 03

Manufacturer:

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

SRN Manufacturer - DE-MF-000005127

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 066097 0106 Rev. 03

Report No.:	713258363_G10change
Preceding Certificate No.:	G10 066097 0106 Rev. 02
Valid from:	2023-11-23
Valid until:	2025-10-01
Date of Initial Issuance:	2021-06-16

Issue date: 2023-11-23

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Ceaicovschi Tudor
Date: 2025.03.11 16:26:58 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 066097 0106 Rev. 03

Classification:	Class IIb
Device Group:	Z120902 - HAEMODIALYSIS INSTRUMENTS
Intended Purpose:	Equipment for extracorporeal blood treatments to administer and remove substances and body fluids

Classification:	Class IIb
Device Group:	D99 - DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES - OTHER
Intended Purpose:	Liquid concentrates for the cleaning, decalcification and heat-disinfection of the fluid pathways of hemodialysis machines

Classification:	Class IIb
Device Group:	Z120990 - VARIOUS NEPHROLOGY AND HAEMODIALYSIS INSTRUMENTS
Intended Purpose:	Production of water for diluting hemodialysis concentrates

Classification:	Class IIb
Device Group:	F0499 - DIALYSIS CONCENTRATES - OTHER
Intended Purpose:	Ready-to-use solution for extracorporeal blood treatment

Classification:	Class IIb
Device Group:	F0306 - CONTINUOUS DIALYSIS KITS
Intended Purpose:	Sets consisting of extracorporeal circuits and filters for continuous blood purification treatment

Classification:	Class IIb
Device Group:	F040201 - DIALYSIS CONCENTRATES, BASIC SOLUTIONS, POWDER
Intended Purpose:	Alkaline concentrates to be used in bicarbonate hemodialysis or hemodiafiltration

Classification:	Class IIb
Device Group:	F010601 - DIALYSERS - UFC < 18 ml/h/mmHg
Intended Purpose:	Dialyzers to be used in hemodialysis and hemo(dia)filtration

Classification:	Class IIb
Device Group:	F010602 - DIALYSERS - UFC = 18 - 35 ml/h/mmHg
Intended Purpose:	Dialyzers to be used in hemodialysis and hemo(dia)filtration

Classification:	Class IIb
Device Group:	F010603 - DIALYSERS - UFC > 35 ml/h/mmHg

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
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TÜV SÜD
Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 066097 0106 Rev. 03

Intended Purpose:	Dialyzers to be used in hemodialysis and hemo(dia)filtration
Classification:	Class IIb
Device Group:	F040101 - DIALYSIS CONCENTRATES, ACID SOLUTIONS, NON-STERILE
Intended Purpose:	Acidic concentrate for bicarbonate hemodialysis or hemodiafiltration
Classification:	Class IIb
Device Group:	F040202 - DIALYSIS CONCENTRATES, BASIC SOLUTIONS, LIQUID
Intended Purpose:	Alkaline concentrates to be used in bicarbonate hemodialysis or hemodiafiltration
Classification:	Class IIb
Device Group:	B030201 - PLASMAPHERESIS DEVICES AND KITS
Intended Purpose:	Apheresis set
Classification:	Class IIa
Device Group:	F020102 - ARTERIOVENOUS DIALYSIS LINES, TWO NEEDLES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	F020104 - REINFUSION DIALYSIS LINES
Intended Purpose:	-
Classification:	Class IIa
Device Group:	F020199 - ARTERIOVENOUS DIALYSIS LINES FOR HAEMODIALYSIS - HAEMOFILTRATION - HAEMODIAFILTRATION - OTHER
Intended Purpose:	-
Classification:	Class IIa
Device Group:	B030201 - PLASMAPHERESIS DEVICES AND KITS
Intended Purpose:	-
Classification:	Class IIa
Device Group:	F900301 - HAEMODIALYSIS ADAPTORS
Intended Purpose:	-

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TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 066097 0106 Rev. 03

Classification: Class IIa
Device Group: A010401 - ARTERIOVENOUS FISTULA NEEDLES
Intended Purpose: -

Classification: Class IIa
Device Group: C010280 - CENTRAL VENOUS CATHETERS - ACCESSORIES
Intended Purpose: -

Classification: Class IIa
Device Group: F0305 - HAEMOPERFUSION KITS
Intended Purpose: -

Classification: Class IIa
Device Group: F0301 - HAEMOFILTRATION-HAEMODIAFILTRATION KITS
Intended Purpose: -

Classification: Class IIa
Device Group: F0303 - HAEMODIALYSIS KITS
Intended Purpose: -

Classification: Class IIa
Device Group: B0380 - APHERESIS DEVICES - ACCESSORIES
Intended Purpose: -

Classification: Class IIa
Device Group: F0306 - CONTINUOUS DIALYSIS KITS
Intended Purpose: -

Classification: Class IIa
Device Group: F0307 - ULTRAFILTRATION KITS
Intended Purpose: -

Classification: Class IIa
Device Group: F020180 - ARTERIOVENOUS DIALYSIS LINES FOR HAEMODIALYSIS - HAEMOFILTRATION - HAEMODIAFILTRATION - ACCESSORIES
Intended Purpose: -

Classification: Class IIa

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(Class IIa and Class IIb Devices)

No. G10 066097 0106 Rev. 03

Device Group: A010499 - DIALYSIS NEEDLES - OTHER
Intended Purpose: -

Classification: Class IIa
Device Group: B030299 - APHERESIS THERAPY DEVICES - OTHER
Intended Purpose: -

Classification: Class IIa
Device Group: B0399 - APHERESIS DEVICES - OTHER
Intended Purpose: -

Classification: Class IIa
Device Group: F020101 - ARTERIOVENOUS DIALYSIS LINES, ONE NEEDLE
Intended Purpose: -

Classification: Class IIa
Device Group: F0199 - HAEMODIALYSIS FILTERS - OTHER
Intended Purpose: -

Classification: Class IIa
Device Group: Z120990 - VARIOUS NEPHROLOGY AND HAEMODIALYSIS INSTRUMENTS
Intended Purpose: -

The validity of this certificate depends on conditions and/or is limited to the following: .None.

Revision History:

Rev.	Dated	Report	Description
00	2021-06-16	713175105	-
01	2022-03-03	713175105	-
02	2023-02-20	713221085_DIV_G10change	-
03	2023-11-23	713258363_G10change	Supplemented: Device(s)/group of device(s) added

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

Wir

We

B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germany
SRN (Single Registration No.) DE-MF-000005127

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

hereby declare in our own responsibility
that the product/s

Basis-UDI-DI: 403923900000016232G

Basic-UDI-DI: 403923900000016232G

Sterile Bicarbonatlösungen
(Artikelnummern siehe Anlage I)

Sterile Bicarbonate Solution
(article numbers see attachment I)

mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745
übereinstimmt/übereinstimmen

is/are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745

Konformitätsbewertungsverfahren
nach Anhang IX mit ausnahme der nummer (II)
der oben genannten Verordnung

Conformity Assessment Procedure
according to annex IX excluding (II)
of the Regulation named above

Klassifizierung
gemäß Anhang VIII der oben genannten Verordnung
Klasse IIb Regel 3

Classification
according to annex VIII of the Regulation named above
Class IIb Rule 3

EU-Zertifikat Nr.
G10 066097 0106 Rev. 03

EU Certificate No.
G10 066097 0106 Rev. 03

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

Notified Body
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 München, Germany
Identification number 0123

Datum der ersten CE-Kennzeichnung:
2023-03

Date of first CE-marking:
2023-03

Doc #: 300/21-RA-sb
Doc Rev #: 2.0
Rev date: 2023-12-01

Doc #: 300/21-RA-sb
Doc Rev #: 2.0
Rev date: 2023-12-01

Gültigkeit dieser Erklärung:
vom 2023-12-11
bis 2025-10-01

Validity of this declaration:
from 2023-12-11
until 2025-10-01

Glandorf, 2023-12-07

Matthias Mansla
Site Manager
B.Braun Avitum AG site Glandorf

Mirandola, 2023-12-04

Chiara Bergamini
Vice President Regulatory Affairs

Anlage I / Attachment I

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

Glandorf, 2023-12-07

Matthias Mansla
Site Manager
B.Braun Avitum AG site Glandorf

Mirandola, 2023-12-04

Chiara Bergamini
Vice President Regulatory Affairs

Cytosorbents, Inc.
305 College Road East
Princeton, NJ 08540
USA

Your ref.
Our ref. MED/09-2023
Tel. +31 88 96 83 009
Fax +31 88 96 83 100
E-mail medical.nl@dekra.com

Arnhem, 14 September 2023

Subject: Notified Body Confirmation Letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DEKRA Certification B.V., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0344 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Cytosorbents, Inc.
305 College Road East
Princeton, NJ 08540
USA
SRN Number (if available): US-MF-000002213

Former Name/Address on MDD/AIMD certificates:
Cytosorbents, Inc.
7 Deer Park Dr., Suite K
Monmouth Jct., NJ 08852
USA

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

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

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

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

On behalf of the Notified Body,

Jie Gao
Project Manager

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

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
CytoSorb 300 mL Device (Basic UDI-DI: 123000000630-00313D) **ECOS-300CY Device (Basic UDI-DI: 123000000630-00613N)** **PerSorb for PerLife Device (Basic UDI-DI: 123000000630-02313P)**	Class IIb excluding Class IIb implantable non-WET	N/A	3804606CE01; NB# 0344

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Certification Notice (No. + Ver.)	Action
2023/09/14	3804606CN28.1	Initial issue

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
- Dialysis of ex vivo organ perfusion solutions

Initial date: 25 March 2011
Revision date: 9 June 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

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

Concord, CA, 08 February 2023

Cytosorbents, Inc.
305 College Road East
Princeton, NJ, 08540 USA
USA

To Whom It May Concern:

The purpose of this letter is to outline the facility status of the manufacturer Cytosorbents, Inc. ("Cytosorbents" or "the manufacturer").

Cytosorbents holds the following certificates issued by DEKRA.

CE Certificates

Certificate number	Scope and product categories	Annex	Class & rule
3804606CE01, expiry 26 May 2024	Polymer Based Adsorption Systems • Cytokine, Bilirubin, and Myoglobin Adsorption • P2Y12 Inhibitor-Ticagrelor Removal • Rivaroxaban Removal • Dialysis of ex vivo organ perfusion solutions	Annex II	Class IIb, rule 3

QMS Certificates

Certificate number	Scope of certificate	QS Standard(s)
3819503, expiry 20 September 2025	Design, development, manufacture and distribution of selectively adsorbent polymer cartridges for dialysis of physiological fluids for the area of extracorporeal therapy	EN ISO 13485:2016

In September 2022, the manufacturer moved their main location from 7 Deer Park Dr., Suite K Monmouth Jct., NJ 08852 to 305 College Road East, Princeton, NJ, 08540. This update was reviewed and accepted by DEKRA as a part of the manufacturer's 2022 surveillance assessment. Acceptance of this change is reflected via the new address on revised QMS certificate #3818503.

As per MDR 2017/745, Article 120(1), the corresponding CE certificate 3804606CE01 could not be updated, as this change occurred after 26 May 2020. To account for DEKRA's review and acceptance of this change, the manufacturer's certification notice 3804606CN shows on page 1

section 1 the name of the certification hold as well as the former name and address on MDD certificates.

I hope this letter sufficiently clarifies Cytosorbent's facility status. Should you have addiitonal questions, please contact the undersigned at kate.moustakas@dekra.com.

With kind regards,

Catherine Moustakas
Managing Director – DEKRA Medical US

CytoSorbents, Inc.

305 College Road East
Princeton, NJ 08540
P 732.329.8885
F 732.329.8650
www.cytosorbents.com

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	CytoSorbents, Inc.
Manufacturer address and contact details	305 College Road East, Princeton, NJ 08540 USA
Single Registration Number (SRN) (if available)	US-MF-000002213

Authorised Representative name (if applicable)	ICON (LR) Limited
Authorised Representative address and contact details	South County Business Park Leopardstown, Dublin 18 D18XSR3 Ireland
Single Registration Number (SRN) (if available)	IE-AR-000006507

Notified body name (if applicable)	DEKRA□ See attached schedule
Notified body number (if applicable)	0344□ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	3804606CE01□ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	May 26, 2024□ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

CytoSorbents, Inc.

305 College Road East
Princeton, NJ 08540
P 732.329.8885
F 732.329.8650
www.cytosorbents.com

End date of extended validity/transition period	December 31, 2028□ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

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

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

CytoSorbents, Inc.

305 College Road East
Princeton, NJ 08540
P 732.329.8885
F 732.329.8650
www.cytosorbents.com

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☒ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

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

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

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

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

Signed for and on behalf of the manufacturer:

Full Company Name: CytoSorbents Inc.

Location & Date: 305 College Road East, Princeton, NJ 08540, USA, 09/20/2023

Signature, Print Name, Title

Matthew J. Gilliland, Matthew J. Gilliland, Senior Director, Quality/Quality Sy...

CytoSorbents Incorporated
305 College Road E
Princeton, NJ 08540
www.CytoSorbents.com

Contact Details (at least email)

MatthewG@CytoSorbents.com

CytoSorbents, Inc.

305 College Road East
Princeton, NJ 08540
P 732.329.8885
F 732.329.8650
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Schedule of Devices

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

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
CytoSorb 300 mL	3804606CE01	May 26, 2024	DEKRA - 0344	DEKRA - 0344	12/31/2028	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)