# 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

Digitally signed by Ceaicovschi Tudor
Date: 2024.07.11 09:04:49 EEST
Reason: MoldSign Signature
Location: Moldova



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

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# 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
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Certification Manager



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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<br>• Cytokine, Bilirubin, and Myoglobin Adsorption<br>• P2Y12 Inhibitor-Ticagrelor Removal<br>• Rivaroxaban Removal<br>• 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