

# EC Certificate



**Full Quality Assurance System**  
**MDD Annex II excl. 4**

Registration No.: HD 1220002-1

Manufacturer: Vasomedical Inc.  
137 Commercial Street, Suite 200  
Plainview NY 11803  
USA

Products: Enhanced External Counterpulsation (EECP) Therapy Systems, Patient Monitors, Ambulatory Electrocardiographs, Ambulatory Blood Pressure Recorders

Replaces Approval, Registration No.: HD 60143008 0001

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. 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.

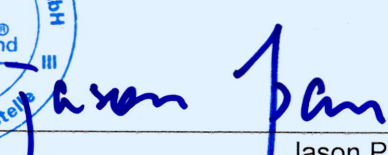
Report No.: 15078287 010

Effective date: 2020-12-30

Expiry date: 2024-05-26

Issue date: 2020-12-30



  
Jason Pan  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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The scope of certification includes the following manufacturing sites:

| No. | Location   | Product groups manufactured   |
|-----|--|---|
| /01 | BIOX Instruments Co., Ltd.<br>100 Dicui Road, 530 Building 1,<br>19th Floor, Binhu District, Wuxi,<br>214072 Jiangsu<br>P.R. China | Enhanced External Counterpulsation (EECP)<br>Therapy Systems, Patient Monitors,<br>Ambulatory Electrocardiographs, Ambulatory<br>Blood Pressure Recorders |

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TÜV Rheinland LGA Products GmbH • 51105 Köln

Vasomedical Inc.  
137 Commercial Street, Suite 200  
Plainview NY 11803  
USA

Contact

Tel. +49 911 655-5225

Mail: service  
@de.tuv.com

Date February 01, 2021

**Application for: Vollst. QMS, Anhang II MDD**

Certificate No.: HD 1220002-1

Requirement : Richtlinie 93/42/EWG

Dear Madame or Sir

Enclosed please find the new certificate No. HD 1220002-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

Jason Pan  
Certification body

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Germany

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