

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60107884 0001

**Report No.:** 15078287 002

**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

(see attachment for additional sites included)

Replaces Approval, Registration No.: HD 60100244 0001

**Expiry Date:** 2020-03-22

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.

**Effective Date:** 2016-02-25

**Date:** 2016-02-25



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

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

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60107884 0001  
**Report No.:** 15078287 002

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

**Sites included:**

Life Enhancement Technology Ltd.  
125 Zhangcha 1st Road, Bldg. 5, 3/F, Foshan City,  
Guangdong 528051, China

Design and Development, Manufacture of  
Enhanced External Counterpulsation (EECP) Therapy Systems

BIOX Instruments Co., Ltd.  
4/F No.45 Liangxi Road, Wuxi, Jiangsu 214062, China

Design and Development, Manufacture of  
Patient Monitors, Ambulatory Electrocardiographs,  
Ambulatory Blood Pressure Recorders

**Date:** 2016-02-25

