

# Certificate of Approval

This is to certify that the Management System of:

**LeMaitre Vascular, Inc.**

63 Second Avenue, Burlington, MA, 01803, United States

has been approved by LRQA to the following standards:

ISO 13485:2016



David Derrick - Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 15 January 2019

Expiry date: 31 December 2021

Certificate identity number: 10166853

Certificate approval No: UQA 4000085

Original approval(s):

ISO 13485 – 14 June 2005

Product number: ISO 13485 – 0011617

The scope of this approval is applicable to:

Design and Manufacture of Angioscopes and Accessories/Adaptors, Embolectomy Catheters, Irrigation Catheters, Cholangiogram Catheters, Occlusion Catheters, Synthetic Vascular Grafts, Synthetic Vascular Patches, Biologic Patches, Non-Occlusive Modeling Catheters, Surgical Clips, Surgical Clip Removers, Carotid Shunts, Endarterectomy Devices, Contrast Injectors, Tape Measuring Rulers and Calipers, Valvulotomes, Surgical Systems for Peripheral Vein Removal and Vein Strippers for Cardiovascular, Gastroenterology, Urology, Neurosurgery, General and Plastic Surgery Applications.



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# Certificate Schedule

Certificate identity number: 10166853

| Location   | Activities  |
|--|---|
| 63 Second Avenue, Burlington, MA, 01803, United States | ISO 13485:2016<br>Design and Manufacture of Angioscopes and Accessories/Adaptors, Embolectomy Catheters, Irrigation Catheters, Cholangiogram Catheters, Occlusion Catheters, Synthetic Vascular Grafts, Synthetic Vascular Patches, Surgical Clips, Surgical Clip Removers, Carotid Shunts, Endarterectomy Devices, Contrast Injectors, Valvulotomes, and Surgical Systems for Peripheral Vein Removal Cardiovascular, Gastroenterology, Urology, Neurosurgery, General and Plastic Surgery Applications. |
| 53 Second Avenue, Burlington, MA, 01803, United States | ISO 13485:2016<br>Design and Manufacture of Synthetic Vascular Grafts, Tape Measuring Rulers and Calipers. Packaging of Medical Devices. Product Testing.   |
| 2 Fourth Avenue, Burlington, MA, 01803, United States  | ISO 13485:2016<br>Product Packaging, Storage and Distribution.  |
| 43 Second Avenue, Burlington, MA, 01803, United States | ISO 13485:2016<br>Design and Manufacture of Biologic Patches. Sales Services and Administration.  |



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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 060725 0003 Rev. 00**

## Manufacturer:

**LeMaitre Vascular, Inc.**

63 Second Avenue  
Burlington MA 01803  
USA

**Product Category(ies):** Single Lumen Embolectomy Catheter; Silicone Single Lumen Embolectomy Catheter; Irrigation Occlusion Catheter; Occlusion Catheter; Aortic Occlusion Catheter; Distal Perfusion Catheter; Cholangiogram Catheter; Over the Wire Valvulotome; Valvulotome; Contrast Injector; Endarterectomy Devices; Dissectors; Retrieval Device; Dissection/ Transection Device; Universal Clip Remover; Disposable Angioscope; Carotid Shunts.

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.:**

72147220

**Valid from:**

2020-02-18

**Valid until:**

2021-12-31

**Date,**

2020-02-18

Christoph Dicks  
Head of Certification/Notified Body

ZERTIFIKAT • CERTIFICATE • CERTIFICADO • CERTIFIKAT • 認證證書



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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 060725 0003 Rev. 00**

## Facility(ies):

LeMaitre Vascular, Inc.

63 Second Avenue, Burlington MA 01803, USA

LeMaitre Vascular Inc

53 Second Ave, Burlington MA 01803, USA

LeMaitre Vascular Inc

43 Second Ave, Burlington MA 01803, USA

LeMaitre Vascular Inc

2 Fourth Ave, Burlington MA 01803, USA

-/-

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.****CE 79407****Issued To:**

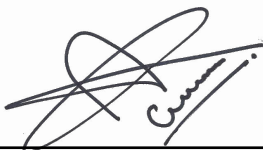
**Cardial SAS**  
**Subsidiary of C.R. Bard Inc.**  
**28 Rue de la Télématique BP 746**  
**Saint-Etienne Cedex 9**  
**42950**  
**France**

In respect of:

**Design, development and manufacture of vascular prostheses, surgical glue and surgical instruments for vascular procedures.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **2004-02-11**

Date: **2019-02-28**

Expiry Date: **2024-01-21**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 79407**  
 Date: **2019-02-28**  
 Issued To: **Cardial SAS**  
**Subsidiary of C.R. Bard Inc.**  
**28 Rue de la Télématicque BP 746**  
**Saint-Etienne Cedex 9**  
**42950**  
**France**

| Subcontractor:  | Service(s) supplied          |
|---|------------------------------|
| Sterigenics Belgium<br>(Petit-Rechain) SA<br>Zoning Industriel de Petit-Rechain<br>Avenue Andre Ernst 21<br>Verviers<br>B-4800<br>Belgium | ETO Sterilization            |
| Symatase Biomateriaux<br>Z.I. Les Troques<br>69630 Chaponost<br>France  | Animal Tissues / Derivatives |
| Synergy Health Marseille – Groupe Steris<br>Site de Marseille<br>MIN 712 Les Arnavaux<br>13323 Marseille Cedex 14<br>France               | Gamma Sterilization          |

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# EC Certificate - Full Quality Assurance System

## Certificate History

Certificate No: **CE 79407**  
Date: **2019-02-28**  
Issued To: **Cardial SAS**  
**Subsidiary of C.R. Bard Inc.**  
**28 Rue de la Télématique BP 746**  
**Saint-Etienne Cedex 9**  
**42950**  
**France**

| Date             | Reference Number | Action  |
|------------------|------------------|---|
| 11 February 2004 |                  | First Issue.  |
| 24 June 2009     | 7159991          | Certificate renewal.<br>Removal of Rousselot as a significant subcontractor.<br>Update Isotron France SAS address to reflect their current ISO 13485 certificate. |
| 22 January 2014  | 8073782          | Replacement of Isotron with Synergy Health on list of subcontractors. Certificate renewal.  |
| 25 July 2014     | 8193137          | Addition of Sterigenics Belgium to the list of subcontractors.<br>Removal of Sterigenics (Anse, France) as a significant subcontractor.                           |
| 16 January 2019  | 8992635          | Certificate renewal.  |
| Current          | 7778907          | Traceable to NB 0086.   |

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# Cardial Surgical Glue

GRF - Gelatin Resorcinol Formaldehyde





# Cardial Surgical Glue

## CARDIAL SURGICAL GLUE

Developed for immediate use, this unique chemical glue - which contains no blood derivatives - has been created specifically for vascular surgery. Supplied in a convenient surgical pack, the glue components are blended at the site of application, saving time and reducing waste. The polymerising agent is introduced via a syringe and polymerisation occurs in just 120 seconds. The result is a stable, dependable glue, ideal for joining dissected vessel layers and reinforcing sutures in acute aortic dissections and reinforcing sutures in cardiac and vascular surgery.

## TYPICAL APPLICATIONS

- Dissection of vessel layers
- Support of suture lines during cardiac and vascular procedures
- Suture line support with acute aortic dissections

## CARDIAL SURGICAL GLUE SPECIFICATIONS

|               |   |
|---------------|---|
| Material      | Adhesive – Porcine Gelatin-Resorcinol mixture<br>Polymerizing Agent – Formaldehyde/Glutaraldehyde<br>Syringe – Polypropylene/synthetic Isoprene                     |
| Sterilization | Adhesive – by chemical action of Resorcinol<br>Polymerizing agent – by chemical action between components<br>Syringe, Accessories & Packaging – Ethylene Oxide (EO) |
| Shelf Life    | 2 years   |



The surgical glue will be delivered ready to use and sterile including the following components in each pack:

- 1 Flexible tube containing the Gelatin Resorcinol mixture
- 1 Opaque glass bottle containing the formaldehyde/glutaraldehyde polymerisation agent
- 1 Luer-Lock single-use syringe, 5 ml
- 1 Applicator with Luer-Lock connector for drawing up and applying the polymerisation agent

## ORDERING INFORMATION

|                       | Pack Quantity | Model # |
|-----------------------|---------------|---------|
| Cardial Surgical Glue | 1             | 52000   |



Your Peripheral Vision™

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Manufactured by:  
LeMaitre Cardial SAS  
28 Rue de la Télématique  
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