

# 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 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 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 Product Packaging, Storage and Distribution.
43 Second Avenue, Burlington, MA, 01803, United States	ISO 13485:2016 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

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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:**

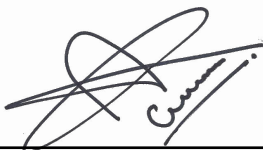
**Cardial SAS**  
**Subsidiary of C.R. Bard Inc.**  
**28 Rue de la Télématique BP 746**  
**Saint-Etienne Cedex 9**  
**42950**  
**France**

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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Page 1 of 1

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 (Petit-Rechain) SA Zoning Industriel de Petit-Rechain Avenue Andre Ernst 21 Verviers B-4800 Belgium	ETO Sterilization
Symatase Biomateriaux Z.I. Les Troques 69630 Chaponost France	Animal Tissues / Derivatives
Synergy Health Marseille – Groupe Steris Site de Marseille MIN 712 Les Arnavaux 13323 Marseille Cedex 14 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. Removal of Rousselot as a significant subcontractor. 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. 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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Page 1 of 1

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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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

## CARDIAL SURGICAL GLUE SPECIFICATIONS

Material	Adhesive – Porcine Gelatin-Resorcinol mixture Polymerizing Agent – Formaldehyde/Glutaraldehyde Syringe – Polypropylene/synthetic Isoprene
Sterilization	Adhesive – by chemical action of Resorcinol Polymerizing agent – by chemical action between components 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



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Manufactured by:  
LeMaitre Cardial SAS  
28 Rue de la Télématique  
42000 Saint Etienne  
France



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F +86 21 61357100

www.lemaitre.com

# LeMaitre® Embolectomy Catheters

## ORDERING INFORMATION

Balloon Diameter	Balloon Volume	Diameter	Color	Length	Guidewire	Model #
<b>Over-the-Wire Embolectomy Catheter</b> Compatible with standard guidewire sizes. Stopcock and syringe included.						
6 mm	0.20 ml	3F	Green	40 cm	.018"	1651-34
6 mm	0.20 ml	3F	Green	80 cm	.018"	1651-38
10 mm	0.75 ml	4F	Red	40 cm	.025"	1651-44
10 mm	0.75 ml	4F	Red	80 cm	.025"	1651-48
12 mm	1.50 ml	5F	White	40 cm	.028"	1651-54
12 mm	1.50 ml	5F	White	80 cm	.028"	1651-58
12 mm	1.50 ml	5F <i>Plus</i>	White	40 cm	.035"	1651-84
12 mm	1.50 ml	5F <i>Plus</i>	White	80 cm	.035"	1651-88
13 mm	1.60 ml	6F	Blue	40 cm	.035"	1651-64
13 mm	1.60 ml	6F	Blue	80 cm	.035"	1651-68
14 mm	1.75 ml	7F	Yellow	80 cm	.038"	1651-78

<b>Single Lumen Embolectomy Catheter</b>						
4.5 mm	0.05 ml	2F	Purple	40 cm		1601-24
4.5 mm	0.05 ml	2F	Purple	60 cm		1601-26
8.0 mm	0.20 ml	3F	Green	40 cm		1601-34
8.0 mm	0.20 ml	3F	Green	80 cm		1601-38
10.5 mm	0.75 ml	4F	Red	40 cm		1601-44
10.5 mm	0.75 ml	4F	Red	80 cm		1601-48
13.0 mm	1.50 ml	5F	White	80 cm		1601-58
13.5 mm	1.60 ml	6F	Blue	80 cm		1601-68
14.0 mm	1.75 ml	7F	Yellow	80 cm		1601-78

<b>NovaSil® Latex-Free Single Lumen Embolectomy Catheter</b>						
4 mm	0.05 ml	2F	Purple	40 cm		1801-24
4 mm	0.05 ml	2F	Purple	60 cm		1801-26
6 mm	0.20 ml	3F	Green	40 cm		1801-34
6 mm	0.20 ml	3F	Green	80 cm		1801-38
9 mm	0.60 ml	4F	Red	40 cm		1801-44
9 mm	0.60 ml	4F	Red	80 cm		1801-48
11 mm	1.00 ml	5F	White	80 cm		1801-58
13 mm	1.60 ml	6F	Blue	80 cm		1801-68
14 mm	1.75 ml	7F	Yellow	80 cm		1801-78

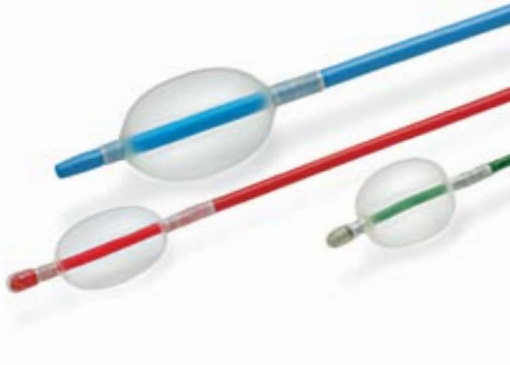
<b>LeMaitre Catheter Rack</b> Catheter rack compatible for all single lumen, over-the-wire, and latex-free catheters.		
Catheter Rack		A3000-00
Wall Mount		A3000-01

These specifications are not intended as a warranty. In the interest of product improvement, these specifications may be changed from time to time without notice. Please consult your sales representative for details.



Your Peripheral Vision™

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# LeMaitre® Embolectomy Catheters

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## For More Information:

Contact your local LeMaitre  
Vascular Sales Representative.

## For Customer Service:

Call 800 628 9470

[www.lemaitre.com](http://www.lemaitre.com)



Your Peripheral Vision™

5F *Plus* featuring two radiopaque bands for visibility



# LeMaitre® Embolectomy Catheters

## A COMPLETE RANGE OF QUALITY CATHETERS:

LeMaitre offers an expanded line of premium quality balloon catheters for rapid removal of emboli and thrombi. Available in Single Lumen, Over-the-Wire, and Latex-Free models, LeMaitre Catheters are:

**Radiopaque.**  
For easy visibility of instrument under fluoroscopy

**Pliable.**  
Eases introduction into difficult anatomy

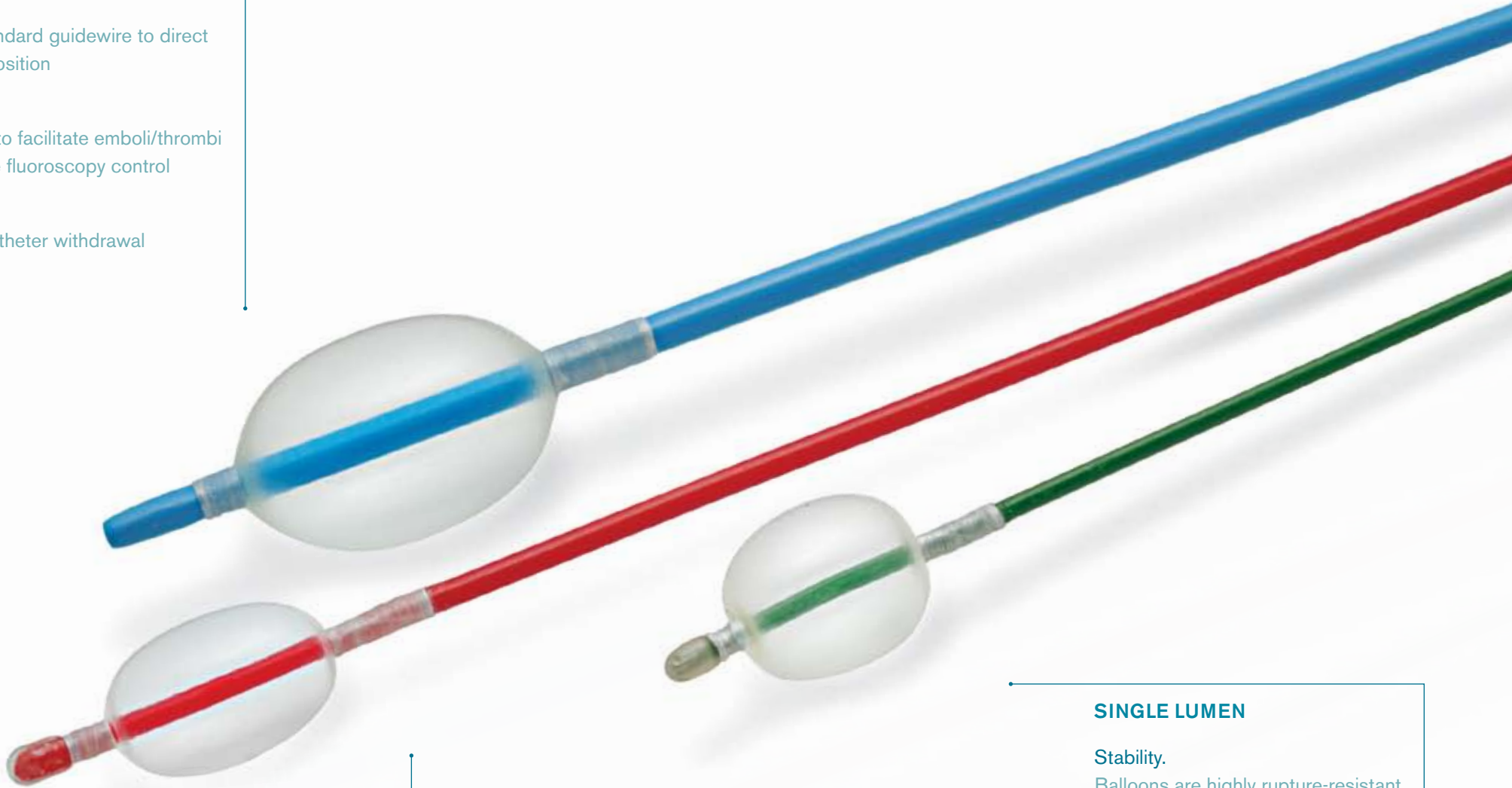
**Sterile.**  
Three-year sterility for latex balloons; five-year for latex-free

### OVER-THE-WIRE

**Guidance.**  
Compatible with standard guidewire to direct catheter to proper position

**Dye Enhancement.**  
Add contrast media to facilitate emboli/thrombi imaging and improve fluoroscopy control

**Irrigation.**  
Lubricates during catheter withdrawal



### SINGLE LUMEN

**Stability.**  
Balloons are highly rupture-resistant

**Concentricity.**  
Balloons are well-centered

**Progressive Inflation.**  
Balloons inflate at consistent rate as volume increases

LeMaitre also offers NovaSil® **LATEX-FREE** Catheters. This line of premium quality silicone balloon catheters provides a latex-free option for latex sensitivity.

### 5F PLUS



- Two radiopaque bands at proximal and distal ends of balloon for enhanced visibility under fluoroscopy
- Compatible with .035" guidewire and 6F introducer