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.

Digitally signed by Captari Vladimir
Date: 2020.05.04 13:03:41 EEST
Reason: MoldSign Signature
Location: Moldova

UKAS MANAGEMENT SYSTEMS
001

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.

UKAS MANAGEMENT SYSTEMS

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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

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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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

-/-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

By Royal Charter

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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By Royal Charter

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 Télématique 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**
Symatese 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.

Cardial
Surgical Glue

GRF - Gelatin Resorcinol Formaldehyde

LeMaitre® VASCULAR

Your Peripheral Vision™

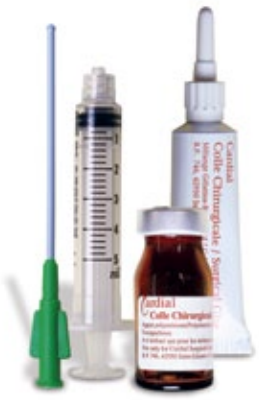
Cardial
Surgical Glue

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/Gluteraldehyde 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/gluteraldehyde 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

LeMaitre VASCULAR
Your Peripheral Vision™

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

CE 0086

LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts. · Germany
T +49 (0)6196 659230
F +49 (0)6196 527072

LeMaitre Vascular SAS
79 avenue de Villiers
75017 Paris · France
T +33 (0)3 44 26 00 41
F +33 (0)3 44 26 07 31

LeMaitre Vascular S.r.l.
Via Leone Tolstoj 86
20098 San Giuliano Milanese (MI)
Italy
T +39 02 988 48 51
F +39 02 984 97 059

LeMaitre Vascular Spain S.L.
Calle Basauri 17
28023 Madrid · Spain
T +34 902 500 037
F +34 91 184 98 71

LeMaitre Vascular Switzerland GmbH
Neuhofstrasse 5A
CH-6340 Baar · Switzerland
T 0800 561 761
F +41 415 608 236

LeMaitre Vascular AS
Dronning Eufemias gt. 16
NO-0191 Oslo · Norway
T +49 (0)6196 659230
F +47 21 54 74 67

LeMaitre Vascular, Inc.
63 Second Avenue
Burlington, MA 01803 · USA
T +1 781 221 2266
F +1 781 221 2223

LeMaitre Vascular GK · Japan
T +81 (0)3 5215 5681
F +81 (0)3 5215 5682

LeMaitre Vascular ULC · Canada
T +1 905 832 8077
F +1 905 303 3903

LeMaitre Vascular PTY LTD · Australia
T +61 (0) 3 9330 4775
F +61 (0) 3 9330 4772

LeMaitre Medical Technology (Shanghai) Co., Ltd · China
T +86 21 61357276
F +86 21 61357100

www.lemaitre.com