

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.



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.



001

EC Certificate – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

LeMaitre Vascular, Inc.

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

has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for Class III products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.



David Derrick - Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

Current Certificate: 01 January 2019

Expiry Date: 30 June 2019

Certificate Identity Number: 10079095

LRQA Notified Body Number: 0088

Original Approval: 25 July 2005

Approval Certificate Number: MDD – 00007399

EC Certificate – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE IDENTITY No.10079095 SCHEDULE

In accordance with the requirements of the Medical Devices Directive
93/42/EEC and the Medical Devices Regulations 2002, UK Statutory
Instrument 2002 No. 618

LeMaitre Vascular, Inc.

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

<u>Class I Sterile Products</u> Vascutape® Glow N' Tell Tape Vascutape® LeMaitre Stent Guide	
<u>Class IIa Products</u> LeMaitre® Single Lumen Emblectomy Catheter LeMaitre® Over the Wire Emblectomy Catheter Novasil® Silicone Single Lumen Emblectomy Catheter TRIVEX System Pruitt® Irrigation Occlusion Catheter Pruitt® Occlusion Catheter Pruitt® Aortic Occlusion Catheter Distal Perfusion Catheter Reddick® Cholangiogram Catheter Reddick® Scoop Tip Cholangiogram Catheter Expandable LeMaitre® Valvulotome Over the Wire Expandable LeMaitre® Valvulotome InvisiGrip® Vein Stripper LeverEdge® Contrast Injector MollRing Cutter® Martin Dissector Periscope® Dissector EndoHelix™ AnastoClip® Universal Clip Remover (single use/sterile) MultiTASC Dissection/Transection Device LeMills Valvulotome HYDRO LeMaitre Valvulotome Disposable Angioscope EZE-SIT Valvulotome	<u>Class IIb Products</u> LifeSpan® Vascular Grafts

EC Certificate – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE IDENTITY No.10079095 SCHEDULE

In accordance with the requirements of the Medical Devices Directive
93/42/EEC and the Medical Devices Regulations 2002, UK Statutory
Instrument 2002 No. 618

Class III Products

AnastoClip AC Closure System
Flexcel® Carotid Shunt
AnastoClip GC Closure System
Pruitt® F3™ Carotid Shunt
Pruitt-Inahara® Outlying Carotid Shunt without
T-PORT
Inahara-Pruitt® Inlying Carotid Shunt without
T-PORT
Pruitt-Inahara® Outlying Carotid Shunt with
T-PORT
Inahara-Pruitt® Inlying Carotid Shunt with T-PORT
AlboGraft™ Vascular Graft
AlboSure™ Vascular Patch
LeMaitre Aortic Occlusion Catheter
XenoSure® Biologic Patch

EC Design Examination Certificate

0088/4000085/00245
0088/4000085/00244
0088/4000085/00306
0089/4000085/00318

0088/4000085/00323

0088/4000085/00323

0088/4000085/00323

0088/4000085/00323

0088/4000085/00329

0088/4000085/00357

0088/4000085/00373

0088/4000085/00375

Schedule Issue: 24

Date of Schedule Issue: 01 January 2019

Certificate Identity Number: 10079095

LRQA Notified Body Number: 0088



David Derrick - Area Operations Manager UK & Ireland

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