



Certificate US21/819944236

The management system of

# LeMaitre Vascular Inc.

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

has been assessed and certified as meeting the requirements of

## ISO 13485:2016 EN ISO 13485:2016

For the following activities

**Design, development, Manufacture, and distribution of Sterile and nonsterile Angioscopes and Accessories/Adaptors, Embolectomy catheters, Irrigation Catheters, Occlusion Catheters, Synthetic Vascular Grafts, Synthetic Patches, Biologic Vascular Grafts, Biologic Patches, Biosynthetic Grafts, Surgical Clips, Surgical Clip Removers, Carotid Shunts, Endarterectomy Devices, Contrast injectors, Tape Measuring Rulers, Valvulotomes, Surgical Systems for Peripheral Vein removal for the areas of peripheral Vascular Surgery, Cardiac Surgery, Neurosurgery, and General Surgery.**  
**Servicing of Surgical Systems for Peripheral Vein Removal.**  
**Distribution of Biologic Patches, Endarterectomy Devices, Embolectomy Catheters, Biologic Vascular Grafts.**

This certificate is valid from 14 February 2022 until 11 February 2024 and remains valid subject to satisfactory surveillance audits. Recertification audit due a minimum of 60 days before the expiration date. Issue 3. Certified since 11 February 2021

This is a multi-site certification. Additional site details are listed on subsequent pages.

Authorised by



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SGS United Kingdom Ltd  
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 [www.sgs.com](http://www.sgs.com)

21HC 13485 MS 0721

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Certificate US21/819944236, continued

# LeMaitre Vascular Inc.

## ISO 13485:2016 EN ISO 13485:2016



Issue 3

**Certified activities are performed by the sites on the list.**

**53 Second Avenue, Burlington, MA, 01803, United States**

**32 Third Avenue, Burlington, MA, 01803, United States**

**2 Fourth Avenue, Burlington, MA, 01803, United States**

**43 second avenue, Burlington, MA 01803, United States**



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## DECLARATION OF CONFORMITY

Application of Council Directive(s): 93/42/EEC, as amended by 2007/47/EC

Standard(s) to which conformity is declared: ISO 13485: 2016  
93/42/EEC Annex II  
Other applicable Standards in ERC D1719

Notified Body: SGS Belgium NV (1639)  
Noorderlaan 87,  
BE-2030 Antwerpen  
Belgium

Manufacturer: **LeMaitre Vascular, Inc.**

Manufacturer Address: 63 Second Avenue  
Burlington, MA 01803  
USA.

Name of Device: **LifeSpan ePTFE Vascular Grafts**

Intended Use: The LifeSpan Vascular Grafts are indicated for use as a vascular prosthesis only. The grafts are intended for bypass or reconstruction of diseased or occluded blood vessels, or for arteriovenous shunts for blood access.

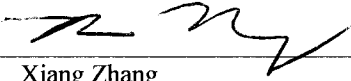
Device Classification: IIb, Rule 8

Type No. / Model No. / Ref. No.: See attached pages

EU Authorized Representative: LeMaitre Vascular GmbH  
Otto-Volger-Str. 5 a/b  
65843, Sulzbach/Ts  
Germany

I, the undersigned, hereby declare that the medical device(s) specified above conform with the Essential Requirements listed in Annex I of the European Council Directive 93/42/EEC dated 14 June 1993 concerning medical devices. This declaration is issued under the sole responsibility of LeMaitre Vascular, Inc.

Place: LeMaitre Vascular, Inc.  
63 Second Avenue  
Burlington, MA 01803 U.S.A.

  
Xiang Zhang  
VP, Regulatory Affairs

Validity Period: February 19, 2021 to May 24, 2024

**List of Applicable LifeSpan Vascular Graft  
Product Model Code**

GR74070	T05020	R06050	T07080C80
GT74070	T05050	R06050C50	T08010
GT74080C70	T05080	R06050CS	T08020
QT46040	T06010	R06050CS5	T08050
QT47030	T06020	R06080	T08050C30
QT47040	T06050	R06080C80	R07080C80
QT47045CS	T06050C30	R07010	R08010
QT47050	T06050C50	R07020	R08020
QT4745CS5	T06050CS	R07050	R08050
QT47050CS	T06080	R07050C50	R08050C50
R05010	T06080C50	R07050CS	R08050CS
R05020	T06080C80	R07080	R08050CS30
R05050	T06080CS60	R08080C80	R08080
R05050CS5	T07010	R10080	T08050C50
R05080	T07020	R10080C80	T08080
R06010	T07050	RS47050	T08080C50
R06015CS	T07050C30	RS47050CS	T08080C80
R06020	T07050C50	RS47050CS5	T10080
R06030	T07080	T05010	T10080C80
R06040CS	T07080C50		

## DECLARATION OF CONFORMITY

Application of Council Directive(s): 93/42/EEC, as amended by 2007/47/EC

Standard(s) to which conformity is declared: ISO 13485: 2016  
93/42/EEC Annex II  
Other applicable Standards in ERC D1321-00

Notified Body: SGS Belgium NV (1639)  
Noorderlaan 87  
BE-2030 Antwerpen  
Belgium

Manufacturer: **LeMaitre Vascular, Inc.**  
Manufacturer Address: 63 Second Avenue  
Burlington, Massachusetts 01803  
U.S.A.

Name of Device: **Pruitt® F3 and F3-S Carotid Shunts**

Intended Use: The Pruitt F3 and F3-S Carotid Shunts are indicated for use in carotid endarterectomy as a temporary conduit to allow for blood flow between the common and internal carotid arteries.


Device Classification: Class III, Rule 7, Indent 1

Type No. / Model No. / Ref. No.: F3 Shunt - 2011-10, 2011-12, 2012-10, 2012-11, 2012-12, 2012-13, 2013-10  
F3-S Shunt – 2014-10, 2015-10

EU Authorized Representative: LeMaitre Vascular GmbH  
Otto-Volger-Str. 5 a/b  
65843, Sulzbach/Ts  
Germany

I, the undersigned, hereby declare that the medical device(s) specified above conform with the Essential Requirements listed in Annex I of the European Council Directive 93/42/EEC dated 14 June 1993 concerning medical devices. This declaration is issued under the sole responsibility of LeMaitre Vascular, Inc.

Place: LeMaitre Vascular, Inc.  
63 Second Avenue  
Burlington, MA 01803 U.S.A.

  
Xiang Zhang  
Vice President, Regulatory Affairs

Validity of the Certificate: May 25, 2021 to May 24, 2024

## DECLARATION OF CONFORMITY

Application of Council Directive(s): 93/42/EEC, as amended by 2007/47/EC  
EU 722/2012

Standard(s) to which conformity is declared: EN ISO 13485: 2016  
MDD Annex II  
Other applicable Standards in ERC D1752

Notified Body: TUV SUD Product Service GmbH (0123)  
Ridlerstraße 65  
80339 Munich  
Germany

Manufacturer: **LeMaitre Vascular, Inc.**  
Manufacturer Address: 63 Second Avenue  
Burlington, MA 01803  
USA.

Name of Device: **XenoSure Biologic Patch**

Intended Use: The XenoSure Biologic Patch is intended for use as a surgical patch material for vascular reconstruction or vessel patching during surgical procedures such as carotid endarterectomy.

Indication for Use: The XenoSure Biologic Patch is indicated for the following conditions: Carotid Stenosis; Aneurysm; Weakened or damaged peripheral arteries.

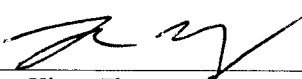
Device Classification: III, Rule 17 and Rule 8

Type No. / Model No. / Ref. No.: See attached page

EU Authorized Representative: LeMaitre Vascular GmbH  
Otto-Volger-Str. 5 a/b  
65843, Sulzbach/Ts  
Germany

I, the undersigned, hereby declare that the medical device(s) specified above conform to the Essential Requirements listed in Annex I of the European Council Directive 93/42/EEC dated 14 June 1993 concerning medical devices. This declaration is issued under the sole responsibility of LeMaitre Vascular, Inc.

Place: LeMaitre Vascular, Inc.  
63 Second Avenue  
Burlington, MA 01803 U.S.A.

  
Xiang Zhang  
VP, Regulatory Affairs

Validity Period: May 21, 2021 to May 26, 2024

### List of Model Numbers

Model Number
1BV6
0.6BV8
0.8BV8
1BV10
2BV9
1BV14
1.5BV10
4BV4
4BV6
6BV8
8BV14
10BV16
2.5BV15
5BV10
12BV25

Responsible	Description of Change	ECO#	Revision	Date
X. Zhang	Initial release of DOC	2147	A	05/01/2014
X. Zhang	Add additional sizes	3315	B	08/22/2016
X. Zhang	Add additional sizes	3651	C	12/6/2017
X. Zhang	Add EU 722/2012	4094	D	02/03/2019
A Gadgil	Update notified body to TUV SUD. Add certificate validity and reference to the product ERC.	CO5255	E	See the last page

EC Certificate Full Quality Assurance System: Certificate US21/819944244

The management system of

# LeMaitre Vascular Inc.

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

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

**The scope of registration appears on page 2 of this certificate**

This certificate is valid from 24 May 2021 until 24 May 2024  
and remains valid subject to satisfactory surveillance audits.  
Issue 2. Certified since 11 February 2021.

Certification is based on reports numbered WW/MC 616691

This is a multi-site certification.  
Additional site details are listed on the subsequent page.

Authorised by

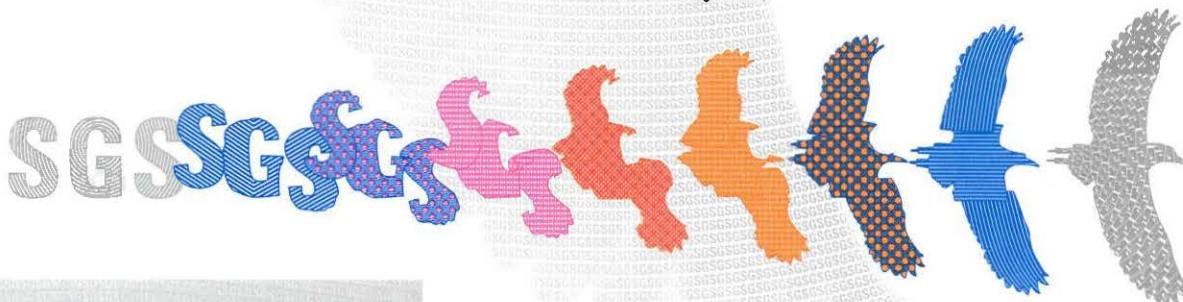
Global Medical Devices Head of Notified Body

### SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium  
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LPMD5007 - Certificate CE1639 Annex II-4\_EN rev. 02

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Certificate US21/819944244 continued

# LeMaitre Vascular Inc.

## Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

**Sterile LifeSpan ePTFE Vascular Graft, Flexcel Carotid Shunt, Pruitt F3 and F3-S Carotid Shunt, AnastoClip AC and GC Closure System includes the Applier and the Clip Remover**

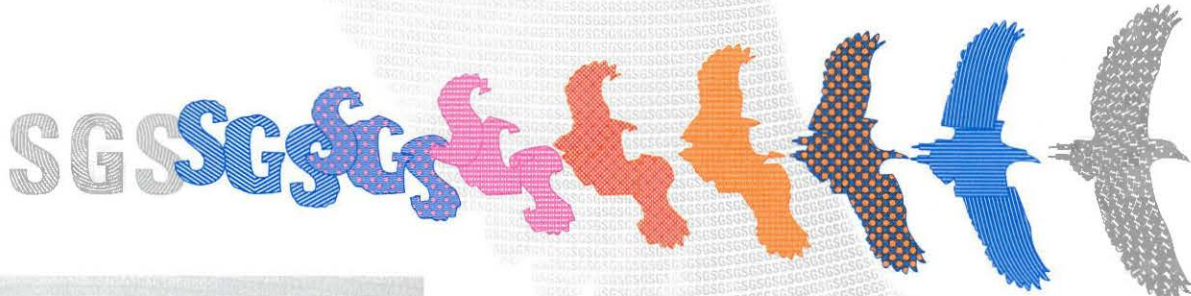
Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

**53 Second Avenue, Burlington, MA, 01803, United States**

**32 Third Avenue, Burlington, MA, 01803, United States**

**2 Fourth Avenue, Burlington, MA, 01803, United States**



# LeMaitre Vascular Inc.

63 Second Avenue  
Burlington, MA  
USA 01803

Device Identification:  
**Pruitt F3 and F3-S Carotid Shunt**

Intended Purpose of Device:

**The Pruitt F3 and F3-S Carotid Shunts are for use in carotid endarterectomy as a temporary conduit to allow for blood flow between the common and internal carotid arteries.**

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC

on Medical Devices, Annex II section 4

It is certified that the manufacture's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 21 May 2021 until 24 May 2024

Issue 1

Certification is based on reports numbered WW/PCI 616726 dated 06 April 2021  
Addenda to that report have been issued on the following dates:

Addendum Date  
N/A

Reason for Addendum  
N/A

Authorised by

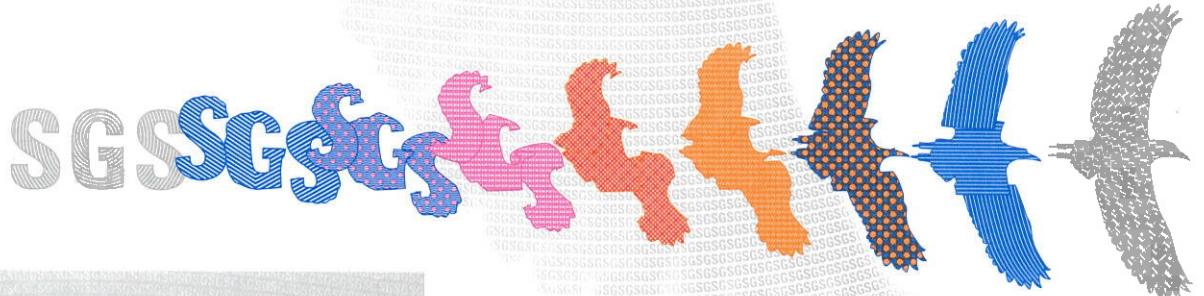
Global Medical Devices Head of Notified Body

## SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD6009 - Certificate CE1639 Annex II section 4 ECDE Rev. 2

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Product Service

Add value.  
Inspire trust.

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

To whom it may concern

Munich, 2021-06-08

Order No.: 713218224

**Confirmation concerning EC Certificate G1 060725 0020 Rev. 00, G1MS 060725 0017 Rev. 00, G7 060725 0011 Rev. 00, G7AO 060725 0018 Rev. 00 and G7AO 060725 0019 Rev. 00**

We confirm that the following certificates:

**G1 060725 0020 Rev. 00** (valid until 2024-05-26)  
**G7 060725 0011 Rev. 00** (valid until 2024-01-12)  
**G7AO 060725 0018 Rev. 00** (valid until 2024-05-26)  
**G7AO 060725 0019 Rev. 00** (valid until 2024-05-26)  
**G1MS 060725 0017 Rev. 00** (valid until 2024-05-26)

issued to the legal medical device manufacturer:

**LeMaitre Vascular, Inc.**  
**63 Second Avenue**  
**Burlington MA 01803**  
**USA**

cover the Directive 93/42/EEC on Medical Devices with the scope (G1 060725 0020 Rev. 00):

**Single Lumen Embolectomy Catheter; Silicone Single Lumen Embolectomy Catheter; Irrigation Occlusion Catheter; Occlusion Catheter; Aortic Occlusion Catheter; Distal Perfusion Catheter; Over the Wire Valvulotome; Valvulotome; Contrast Injector; Endarterectomy Devices; Dissectors; Retrieval Device; Dissection/Transection Device; Disposable Angioscope; Biologic Patches; Synthetic Vascular Grafts.**

and the following devices:

MD Code	model number	model name
MD 0101_1	1601-24	TufTex Embolectomy Catheter
	1601-26	
	1601-28	
	1601-34	
	1601-38	
	1601-44	
	1601-48	
	1601-58	
	1601-68	
	1601-78	

Registered Office: Munich  
 Trade Register Munich HRB 85 742  
 UniCredit Bank AG · BIC HYVEDEMMXXX  
 IBAN DE13 7002 0270 0048 8522 11  
 VAT ID No. DE129484267  
 Information pursuant to § 2 [1] DL-InfoV  
 (Germany) at [www.tuvsud.com/imprint](http://www.tuvsud.com/imprint)

Supervisory Board:  
 Holger Lindner (Chairman)

Board of Management:  
 Walter Reithmaier (CEO)  
 Dr. Jens Butenandt (CTO)  
 Patrick van Welij (CFO)

Phone: +49 89 5008-4493  
 Fax: +49 89 5008-4108

[www.tuvsud.com/ps](http://www.tuvsud.com/ps)



TÜV SÜD Product Service GmbH  
 Foreign Affairs  
 Ridlerstrasse 65  
 80339 Munich  
 Germany



MD Code	model number	model name
MD 0101_1	1651-34	TufTex Over-The-Wire embolectomy catheter
	1651-38	
	1651-44	
	1651-48	
	1651-84	
	1651-88	
	1651-64	
	1651-68	
	1651-78	
	1801-26	Syntel Silicone Embolectomy Catheter- Regular Tip
	1801-34	
	1801-38	
	1801-44	
	1801-48	
	1801-54	
	1801-58	
	1801-68	
	1801-78	
	A4F00	Syntel Silicone Embolectomy Catheter- Spring Tip
	A4F01	
	A4F02	
	A4F03	
	A4F04	
	A4F05	
	A4F06	
	A4F07	
	A4F08	
	A4538	Syntel Silicone Thrombectomy Catheter
	A4545	
	A4548	
	A4554	
	A4558	
	A4568	
A4518		
A4E01	Syntel Silicone Over-the-Wire Embolectomy Catheter	
A4E02		
A4E03		
A4E04		
A4E05		
A4E06		
A4E07		
A4E08		
A4E09		
A4G02	Latis Silicone Graft Cleaning Catheter	
A4G00		
A4GW6	Latis Silicone Over-the-Wire Graft Cleaning Catheter	
2102-09	Pruitt irrigation occlusion catheter	
2103-36		
2103-46	Pruitt occlusion catheter	
2103-56		
2105-15	Distal perfusion catheter	
MD 0106	1009-00	
	1009-00J	LeMaitre valvulotome
	1010-00	
	1050-00	
	1050-01	LeMills valvultome
	1050-02	
	TIVK2030	EZE-SIT valvulotome
4100-00	LeverEdge contrast injector	



MD Code	model number	model name
MD 0106	4200-40	Mollring cutter
	4200-41	
	4200-42	
	4200-43	
	4200-44	
	4200-45	
	4200-10	Martin dissector
	4200-00	Periscope dissector
	4200-20	Endohelix
	4500-03	MultiTASC dissector
	4500-04	
	4500-05	
	4500-06	
	4500-07	
	4500-08	
4500-09		
4500-10		
MD1104_2	A5000	PeriVu Disposable angioscope
	ANG-080-D10K	

cover the Directive 93/42/EEC on Medical Devices with the scope (G7 060725 0011 Rev. 00):

#### **Catheters for Single Use Aortic Occlusion Catheter**

and the following devices:

LeMaitre Aortic Occlusion Catheter 2107-80  
LeMaitre Aortic Occlusion Catheter 2107-81

cover the Directive 93/42/EEC on Medical Devices with the scope (G7AO 060725 0018 Rev. 00):

#### **Vascular Grafts Synthetic Vascular Graft**

and the following devices:

AMC1506 AlboGraft Knitted Collagen Straight Graft 15cmx6mm [LxD]  
AMC3006 AlboGraft Knitted Collagen Straight Graft 30cmx6mm [LxD]  
AMC4006 AlboGraft Knitted Collagen Straight Graft 40cmx6mm [LxD]  
AMC6006 AlboGraft Knitted Collagen Straight Graft 60cmx6mm [LxD]  
AMC1006 AlboGraft Knitted Collagen Straight Graft 100cmx6mm [LxD]  
AMC4007 AlboGraft Knitted Collagen Straight Graft 40cmx7mm [LxD]  
AMC1508 AlboGraft Knitted Collagen Straight Graft 15cmx8mm [LxD]  
AMC3008 AlboGraft Knitted Collagen Straight Graft 30cmx8mm [LxD]  
AMC4008 AlboGraft Knitted Collagen Straight Graft 40cmx8mm [LxD]  
AMC6007 AlboGraft Knitted Collagen Straight Graft 60cmx7mm [LxD]  
AMC6008 AlboGraft Knitted Collagen Straight Graft 60cmx8mm [LxD]  
AMC1008 AlboGraft Knitted Collagen Straight Graft 100cmx8mm [LxD]  
AMC1510 AlboGraft Knitted Collagen Straight Graft 15cmx10mm [LxD]  
AMC3010 AlboGraft Knitted Collagen Straight Graft 30cmx10mm [LxD]  
AMC4010 AlboGraft Knitted Collagen Straight Graft 40cmx10mm [LxD]  
AMC6010 AlboGraft Knitted Collagen Straight Graft 60cmx10mm [LxD]  
AMC1010 AlboGraft Knitted Collagen Straight Graft 100cmx10mm [LxD]  
AMC1512 AlboGraft Knitted Collagen Straight Graft 15cmx12mm [LxD]  
AMC3012 AlboGraft Knitted Collagen Straight Graft 30cmx12mm [LxD]  
AMC1514 AlboGraft Knitted Collagen Straight Graft 15cmx14mm [LxD]  
AMC3014 AlboGraft Knitted Collagen Straight Graft 30cmx14mm [LxD]  
AMC1516 AlboGraft Knitted Collagen Straight Graft 15cmx16mm [LxD]



AMC3016 AlboGraft Knitted Collagen Straight Graft 30cmx16mm [LxD]  
 AMC1518 AlboGraft Knitted Collagen Straight Graft 15cmx18mm [LxD]  
 AMC3018 AlboGraft Knitted Collagen Straight Graft 30cmx18mm [LxD]  
 AMC1520 AlboGraft Knitted Collagen Straight Graft 15cmx20mm [LxD]  
 AMC3020 AlboGraft Knitted Collagen Straight Graft 30cmx20mm [LxD]  
 AMC1522 AlboGraft Knitted Collagen Straight Graft 15cmx22mm [LxD]  
 AMC3022 AlboGraft Knitted Collagen Straight Graft 30cmx22mm [LxD]  
 AMC1524 AlboGraft Knitted Collagen Straight Graft 15cmx24mm [LxD]  
 AMC4012 AlboGraft Knitted Collagen Straight Graft 40cmx12mm [LxD]  
 AMC3024 AlboGraft Knitted Collagen Straight Graft 30cmx24mm [LxD]  
 AMC1207 AlboGraft Knitted Collagen Bifurcated Graft 12mmx7mm [DxD]  
 AMC1407 AlboGraft Knitted Collagen Bifurcated Graft 14mmx7mm [DxD]  
 AMC1408 AlboGraft Knitted Collagen Bifurcated Graft 14mmx8mm [DxD]  
 AMC1608 AlboGraft Knitted Collagen Bifurcated Graft 16mmx8mm [DxD]  
 AMC1609 AlboGraft Knitted Collagen Bifurcated Graft 16mmx9mm [DxD]  
 AMC1809 AlboGraft Knitted Collagen Bifurcated Graft 18mmx9mm [DxD]  
 AMC1810 AlboGraft Knitted Collagen Bifurcated Graft 18mmx10mm [DxD]  
 AMC2010 AlboGraft Knitted Collagen Bifurcated Graft 20mmx10mm [DxD]  
 AMC2011 AlboGraft Knitted Collagen Bifurcated Graft 20mmx11mm [DxD]  
 AMC2211 AlboGraft Knitted Collagen Bifurcated Graft 22mmx11mm [DxD]  
 AMC2412 AlboGraft Knitted Collagen Bifurcated Graft 24mmx12mm [DxD]  
 ASC3006AlboGraft Knitted Collagen Straight Graft with Removable External Support 30cmx6mm[LxD]  
 ASC4006AlboGraft Knitted Collagen Straight Graft with Removable External Support 40cmx6mm[LxD]  
 ASC6006AlboGraft Knitted Collagen Straight Graft with Removable External Support 60cmx6mm[LxD]  
 ASC8006AlboGraft Knitted Collagen Straight Graft with Removable External Support 80cmx6mm[LxD]  
 ASC3007AlboGraft Knitted Collagen Straight Graft with Removable External Support 30cmx7mm[LxD]  
 ASC4007AlboGraft Knitted Collagen Straight Graft with Removable External Support 40cmx7mm[LxD]  
 ASC6007AlboGraft Knitted Collagen Straight Graft with Removable External Support 60cmx7mm[LxD]  
 ASC8007AlboGraft Knitted Collagen Straight Graft with Removable External Support 80cmx7mm[LxD]  
 ASC3008AlboGraft Knitted Collagen Straight Graft with Removable External Support 30cmx8mm[LxD]  
 ASC4008AlboGraft Knitted Collagen Straight Graft with Removable External Support 40cmx8mm[LxD]  
 ASC6008AlboGraft Knitted Collagen Straight Graft with Removable External Support 60cmx8mm[LxD]  
 ASC8008AlboGraft Knitted Collagen Straight Graft with Removable External Support 80cmx8mm[LxD]  
 ATC1506 AlboGraft Woven Collagen Straight Graft 15cmx6mm[LxD]  
 ATC3006 AlboGraft Woven Collagen Straight Graft 30cmx6mm[LxD]  
 ATC4006 AlboGraft Woven Collagen Straight Graft 40cmx6mm[LxD]  
 ATC6006 AlboGraft Woven Collagen Straight Graft 60cmx6mm[LxD]  
 ATC1508 AlboGraft Woven Collagen Straight Graft 15cmx8mm[LxD]  
 ATC3008 AlboGraft Woven Collagen Straight Graft 30cmx8mm[LxD]  
 ATC4008 AlboGraft Woven Collagen Straight Graft 40cmx8mm[LxD]  
 ATC6008 AlboGraft Woven Collagen Straight Graft 60cmx8mm[LxD]  
 ATC1510 AlboGraft Woven Collagen Straight Graft 15cmx10mm[LxD]  
 ATC3010 AlboGraft Woven Collagen Straight Graft 30cmx10mm[LxD]  
 ATC4010 AlboGraft Woven Collagen Straight Graft 40cmx10mm[LxD]  
 ATC6010 AlboGraft Woven Collagen Straight Graft 60cmx10mm[LxD]  
 ATC1512 AlboGraft Woven Collagen Straight Graft 15cmx12mm[LxD]  
 ATC3012 AlboGraft Woven Collagen Straight Graft 30cmx12mm[LxD]  
 ATC4012 AlboGraft Woven Collagen Straight Graft 40cmx12mm[LxD]  
 ATC1514 AlboGraft Woven Collagen Straight Graft 15cmx14mm[LxD]  
 ATC3014 AlboGraft Woven Collagen Straight Graft 30cmx14mm[LxD]  
 ATC1516 AlboGraft Woven Collagen Straight Graft 15cmx16mm[LxD]  
 ATC3016 AlboGraft Woven Collagen Straight Graft 30cmx16mm[LxD]  
 ATC1518 AlboGraft Woven Collagen Straight Graft 15cmx18mm[LxD]  
 ATC3018 AlboGraft Woven Collagen Straight Graft 30cmx18mm[LxD]  
 ATC1520 AlboGraft Woven Collagen Straight Graft 15cmx20mm[LxD]  
 ATC3020 AlboGraft Woven Collagen Straight Graft 30cmx20mm[LxD]  
 ATC1522 AlboGraft Woven Collagen Straight Graft 15cmx22mm[LxD]  
 ATC3022 AlboGraft Woven Collagen Straight Graft 30cmx22mm[LxD]  
 ATC1524 AlboGraft Woven Collagen Straight Graft 15cmx24mm[LxD]  
 ATC3024 AlboGraft Woven Collagen Straight Graft 30cmx24mm[LxD]  
 ATC1526 AlboGraft Woven Collagen Straight Graft 15cmx26mm[LxD]  
 ATC3026 AlboGraft Woven Collagen Straight Graft 30cmx26mm[LxD]  
 ATC1528 AlboGraft Woven Collagen Straight Graft 15cmx28mm[LxD]  
 ATC3028 AlboGraft Woven Collagen Straight Graft 30cmx28mm[LxD]  
 ATC1530 AlboGraft Woven Collagen Straight Graft 15cmx30mm[LxD]



ATC3030 AlboGraft Woven Collagen Straight Graft 30cmx30mm[LxD]  
 ATC1532 AlboGraft Woven Collagen Straight Graft 15cmx32mm[LxD]  
 ATC3032 AlboGraft Woven Collagen Straight Graft 30cmx32mm[LxD]  
 ATC1534 AlboGraft Woven Collagen Straight Graft 15cmx34mm[LxD]  
 ATC3034 AlboGraft Woven Collagen Straight Graft 30cmx34mm[LxD]  
 ATC1538 AlboGraft Woven Collagen Straight Graft 15cmx38mm[LxD]  
 ATC3038 AlboGraft Woven Collagen Straight Graft 30cmx38mm[LxD]  
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 ATC1407 AlboGraft Woven Collagen Bifurcated Graft 14mmx7mm[DxD]  
 ATC1408 AlboGraft Woven Collagen Bifurcated Graft 14mmx8mm[DxD]  
 ATC1608 AlboGraft Woven Collagen Bifurcated Graft 16mmx8mm[DxD]  
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 ATC2011 AlboGraft Woven Collagen Bifurcated Graft 20mmx11mm[DxD]  
 ATC2211 AlboGraft Woven Collagen Bifurcated Graft 22mmx11mm[DxD]  
 ATC2412 AlboGraft Woven Collagen Bifurcated Graft 24mmx12mm[DxD]  
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 AMC6014 AlboGraft Knitted Collagen Straight Graft 60cmx14mm[LxD]  
 AMC6016 AlboGraft Knitted Collagen Straight Graft 60cmx16mm[LxD]  
 AMC6018 AlboGraft Knitted Collagen Straight Graft 60cmx18mm[LxD]  
 AMC6020 AlboGraft Knitted Collagen Straight Graft 60cmx20mm[LxD]  
 AMC6022 AlboGraft Knitted Collagen Straight Graft 60cmx22mm[LxD]  
 AMC6024 AlboGraft Knitted Collagen Straight Graft 60cmx24mm[LxD]  
 AMC7008 AlboGraft Knitted Collagen Straight Graft 70cmx8mm[LxD]  
 AMC7010 AlboGraft Knitted Collagen Straight Graft 70cmx10mm[LxD]  
 AMC7512 AlboGraft Knitted Collagen Straight Graft 75cmx12mm[LxD]  
 AMC7514 AlboGraft Knitted Collagen Straight Graft 75cmx14mm[LxD]  
 AMC7516 AlboGraft Knitted Collagen Straight Graft 75cmx16mm[LxD]  
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 AMC7524 AlboGraft Knitted Collagen Straight Graft 75cmx24mm[LxD]  
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 ATC6030 AlboGraft Woven Collagen Straight Graft 60cmx30mm[LxD]  
 ATC3036 AlboGraft Woven Collagen Straight Graft 30cmx36mm [LxD]  
 ATC1536 AlboGraft Woven Collagen Straight Graft 15cmx34mm[LxD]  
 ATC6007 AlboGraft Woven Collagen Straight Graft 60cmx7mm[LxD]  
 AMC1206 AlboGraft Knitted Collagen Bifurcated Graft 12mmx6mm[DxD]  
 AMC1507 AlboGraft Polyester Vascular Graft, knited straight, 15cmx7mm  
 AMC3007 AlboGraft Polyester Vascular Graft, knited straight, 30cmx7mm[LxD]  
 AMC7006 AlboGraft Polyester Vascular Graft, knited straight, 70cmx6mm[LxD]  
 AMC1007 AlboGraft Polyester Vascular Graft, knited straight, 100cmx7mm[LxD]  
 AMC8006 AlboGraft Polyester Vascular Graft, knited straight, 80cmx6mm[LxD]  
 ATC1507 AlboGraft Polyester Vascular Graft, woven straight, 15cmx7 mm (LxD)  
 ATC3007 AlboGraft Polyester Vascular Graft, woven straight, 30cmx7mm (LxD)  
 ATC6032 AlboGraft Woven Collagen Straight Graft 60cmx32mm [LxD]  
 ATC6034 AlboGraft Woven Collagen Straight Graft 60cmx34mm [LxD]  
 ATC6038 AlboGraft Woven Collagen Straight Graft 60cmx38mm [LxD]  
 ATC1206 AlboGraft Woven Collagen Bifurcated Graft 12mmx6mm[DxD]  
 AMC4014 AlboGraft Knitted Collagen Straight Graft 40cmx14mm[LxD]  
 AMC4016 AlboGraft Knitted Collagen Straight Graft 40cmx16mm[LxD]  
 AMC4018 AlboGraft Knitted Collagen Straight Graft 40cmx18mm[LxD]



AMC4020 AlboGraft Knitted Collagen Straight Graft 40cmx20mm[LxD]  
 AMC4022 AlboGraft Knitted Collagen Straight Graft 40cmx22mm[LxD]  
 AMC4024 AlboGraft Knitted Collagen Straight Graft 40cmx24mm [LxD]

cover the Directive 93/42/EEC on Medical Devices with the scope (G7AO 060725 0019 Rev. 00):

### Patch of Animal Origin Cardiovascular Patch

and the following devices:

XenoSure Biologic Patch 1BV6  
 XenoSure Biologic Patch 0.6BV8  
 XenoSure Biologic Patch 0.8BV8  
 XenoSure Biologic Patch 1BV10  
 XenoSure Biologic Patch 2BV9  
 XenoSure Biologic Patch 1BV14  
 XenoSure Biologic Patch 1.5BV10  
 XenoSure Biologic Patch 4BV4  
 XenoSure Biologic Patch 4BV6  
 XenoSure Biologic Patch 6BV8  
 XenoSure Biologic Patch 8BV14  
 XenoSure Biologic Patch 10BV16  
 XenoSure Biologic Patch 2.5BV15  
 XenoSure Biologic Patch 5BV10  
 XenoSure Biologic Patch 12BV25  
 XenoSure Biologic Patch 1P6  
 XenoSure Biologic Patch 0.6P8  
 XenoSure Biologic Patch 0.8P8  
 XenoSure Biologic Patch 1P10  
 XenoSure Biologic Patch 2P9  
 XenoSure Biologic Patch 1P14  
 XenoSure Biologic Patch 1.5P10  
 XenoSure Biologic Patch 4P4  
 XenoSure Biologic Patch 4P6  
 XenoSure Biologic Patch 6P8  
 XenoSure Biologic Patch 8P14  
 XenoSure Biologic Patch 10P16

and covers the Directive 93/42/EEC on Medical Devices with the scope (G1MS 060725 0017 Rev. 00):

### Radiopaque Tapes

and the following devices:

MD Code	model number	model name
MD 0106	1100-20	VascuTape Radiopaque Tape
	1100-50	
	1100-00	
	1108-20	
	1102-20	
	1102-50	
	1102-00	
	1109-20	





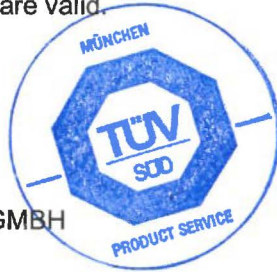
Product Service

With this letter we confirm that the above-mentioned devices are covered by a quality assurance system that has been established by the manufacturer and is certified by the notified body TÜV SÜD Product Service GmbH.

After issuing the declaration of conformity in accordance with the medical device directive 93/42/EEC by the manufacturer, the above-mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area.

The above-mentioned certificates are valid.

*R. Köhler*



Randolf Köhler  
TÜV SÜD PRODUCT SERVICE GMBH  
Medical Health Services  
Foreign Affairs



# 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 0020 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; Over  
the Wire Valvulotome; Valvulotome;  
Contrast Injector; Endarterectomy Devices;  
Dissectors; Retrieval Device;  
Dissection/Transection Device; Disposable  
Angioscope; Biologic Patches; Synthetic  
Vascular Grafts.**

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10607250020Rev.00](http://www.tuvsud.com/ps-cert?q=cert:G10607250020Rev.00)

**Report No.:** 72164019-4

**Valid from:** 2021-05-25

**Valid until:** 2024-05-26

**Date,** 2021-05-25

Christoph Dicks  
Head of Certification/Notified Body



# EC Certificate

EC Design-Examination Certificate  
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)  
(Devices in Class III)

**No. G7AO 060725 0019 Rev. 00**

**Manufacturer:** **LeMaitre Vascular, Inc.**  
63 Second Avenue  
Burlington MA 01803  
USA

**Product:** **Patch of Animal Origin**  
**Cardiovascular Patch**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with the directive 93/42/EEC Annex II (4) and Regulation (EU) 722/2012 on medical devices manufactured utilizing tissues of animal origin. The design of the devices conforms to the requirements of the Directive and the Regulation. If a certificate of the European Directorate for the Quality of Medicines (EDQM) has been issued for the respective material of animal origin, the validity of our certificate is associated with the validity of the EDQM certificate. Any changes of the EDQM certificate need to be reported immediately to TÜV SÜD Product Service GmbH by a change notification. For marketing of these devices an additional Annex II without (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G7AO 060725 0019 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G7AO_060725_0019_Rev._00)

**Report no.:** 72161580  
**Valid from:** 2021-05-21  
**Valid until:** 2024-05-26

**Date,** 2021-05-21

Christoph Dicks  
Head of Certification/Notified Body



# EC Certificate

EC Design-Examination Certificate  
 Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)  
 (Devices in Class III)

**No. G7AO 060725 0019 Rev. 00**

**Model(s): XenoSure Biologic Patch**

Description	Model
XenoSure Biologic Patch	1BV6
XenoSure Biologic Patch	0.6BV8
XenoSure Biologic Patch	0.8BV8
XenoSure Biologic Patch	1BV10
XenoSure Biologic Patch	2BV9
XenoSure Biologic Patch	1BV14
XenoSure Biologic Patch	1.5BV10
XenoSure Biologic Patch	4BV4
XenoSure Biologic Patch	4BV6
XenoSure Biologic Patch	6BV8
XenoSure Biologic Patch	8BV14
XenoSure Biologic Patch	10BV16
XenoSure Biologic Patch	2.5BV15
XenoSure Biologic Patch	5BV10
XenoSure Biologic Patch	12BV25
XenoSure Biologic Patch	1P6
XenoSure Biologic Patch	0.6P8
XenoSure Biologic Patch	0.8P8
XenoSure Biologic Patch	1P10
XenoSure Biologic Patch	2P9
XenoSure Biologic Patch	1P14
XenoSure Biologic Patch	1.5P10
XenoSure Biologic Patch	4P4
XenoSure Biologic Patch	4P6
XenoSure Biologic Patch	6P8
XenoSure Biologic Patch	8P14
XenoSure Biologic Patch	10P16



*LeMaitre<sup>®</sup>*

*2022 EMEA Product Overview*

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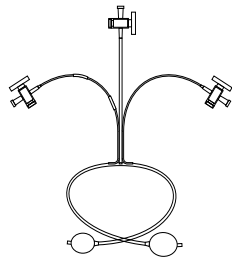
Updated: March 2022

# Pruitt F3<sup>®</sup> Carotid Shunt

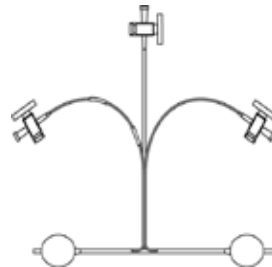
5-year Shelf Life Latex  
2-year Shelf Life Polyurethane

	Diameter	Length	Model #
<b>Pruitt F3<sup>®</sup> Outlying Carotid Shunt (Sterile)</b>			
Shunt with T-Port	8F	31 cm	2013-10
Shunt with T-Port	9F	31 cm	2012-10
Shunt with T-Port	10F	31 cm	2011-10
<b>Pruitt F3<sup>®</sup> Inlying Carotid Shunt (Sterile)</b>			
Shunt with T-Port	9F	15 cm	2012-12
Shunt with T-Port	10F	15 cm	2011-12
<b>Pruitt F3<sup>®</sup>-S Polyurethane Outlying Carotid Shunt (Sterile)</b> Safety balloon not available on polyurethane models.			
Shunt with T-Port	8F	31 cm	2015-10
Shunt with T-Port	9F	31 cm	2014-10

OUTLYING CAROTID SHUNT



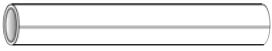
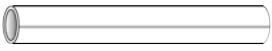
INLYING CAROTID SHUNT



# LifeSpan<sup>®</sup> ePTFE Vascular Grafts



7-year  
Shelf Life

	Diameter	Length	Model #
<b>Regular Wall (Sterile)</b>			
Straight			
	5 mm	20 cm	R05020
	5 mm	50 cm	R05050
	6 mm	10 cm	R06010
	6 mm	20 cm	R06020
	7 mm	20 cm	R07020
	8 mm	20 cm	R08020
	6 mm	30 cm	R06030
	6 mm	50 cm	R06050
	7 mm	50 cm	R07050
	8 mm	50 cm	R08050
	6 mm	80 cm	R06080
	7 mm	80 cm	R07080
	8 mm	80 cm	R08080
	<b>Thin Wall (Sterile)</b>		
Straight			
	5 mm	20 cm	T05020
	6 mm	20 cm	T06020
	6 mm	50 cm	T06050
	7 mm	50 cm	T07050
	8 mm	50 cm	T08050
	6 mm	80 cm	T06080
	7 mm	80 cm	T07080
	8 mm	80 cm	T08080
	10 mm	80 cm	T10080

# XenoSure<sup>®</sup> Biologic Surgical Patch



	Width	Length	Model #
<b>XenoSure<sup>®</sup> Biologic Surgical Patch (Sterile) (Bovine Pericardium) Thickness range 0.350 - 0.750 mm</b>			
Biologic Surgical Patch	4 cm	4 cm	4BV4
Biologic Surgical Patch	4 cm	6 cm	4BV6
Biologic Surgical Patch	6 cm	8 cm	6BV8
Biologic Surgical Patch	5 cm	10 cm	5BV10
Biologic Surgical Patch	8 cm	14 cm	8BV14
Biologic Surgical Patch	2.5 cm	15 cm	2.5BV15
Biologic Surgical Patch	10 cm	16 cm	10BV16

