



Certificate Number US21/819944301  
The management system of

# LeMaitre Vascular Inc.

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

Facility identification number : F005365

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

## MDSAP (ISO 13485:2016)

- Australia:**  
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]
- Brazil:**  
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 /RDC ANVISA n. 67/2009
- Canada:**  
Medical Devices Regulations – Part 1 SOR 98/282
- Japan:**  
MHLW Ministerial Ordinance 169 /Article 4 to Article 68 / PMD Act
- United States:**  
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D



For the following activities and devices

**See second page for the scope.**

The certificate is valid from

Effective Date: 2021-03-29 until Expiry Date: 2024-03-28

And remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2024-02-25

Issue 1. Certified since 2021-03-29

Authorised by L. Henderson  
Business Manager



*L. Henderson*

SGS United Kingdom Ltd  
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK  
t +44 (0)151 3506666 www.sgs.com  
SGS United Kingdom Ltd is an MDSAP authorized auditing organization

MDSAP M2

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Certificate Number US21/819944301, continued

The management system of

# LeMaitre Vascular Inc.

## MDSAP (ISO 13485:2016)

Issue 1



Detailed scope

**Design, development, Manufacturing, 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.**

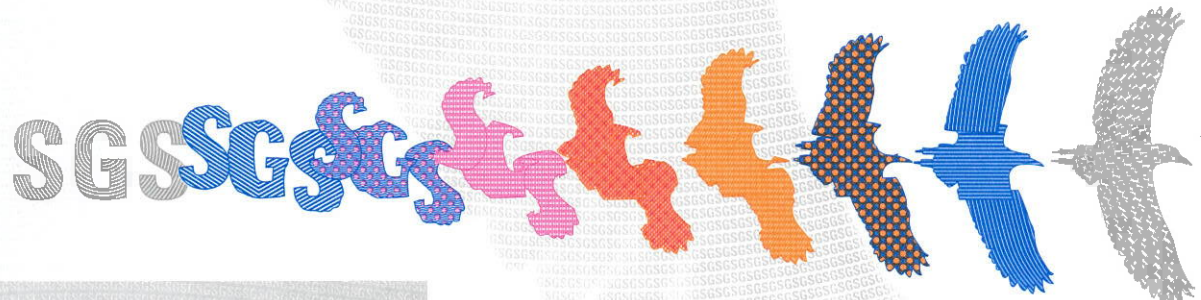
Additional facilities

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

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

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

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



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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

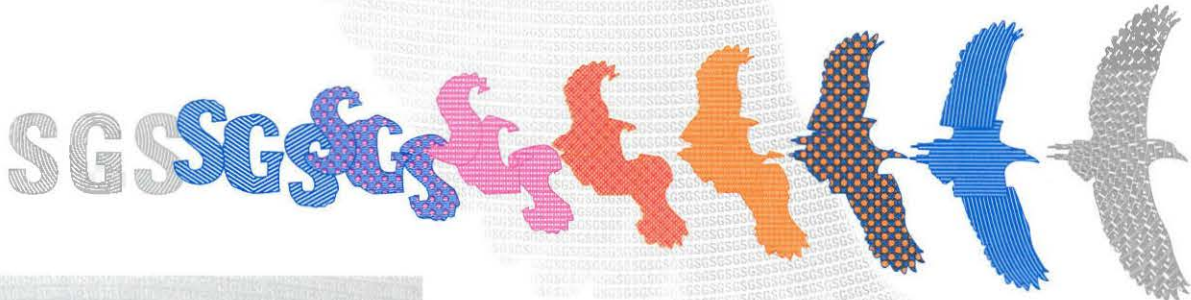
Global Medical Devices Head of Notified Body

### SGS Belgium NV, Notified Body 1639

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

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**

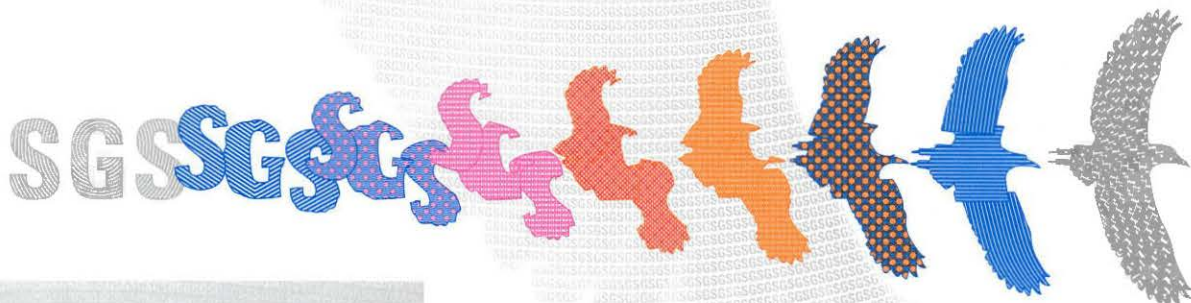
Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

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**





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

- For Peripheral Reconstructions and Vascular Access
- Proven Performance<sup>1</sup>
- Excellent Handling
- Superb Suture Retention









Your Peripheral Vision™



- PERIPHERAL AND VASCULAR ACCESS
- PROVEN PERFORMANCE<sup>1</sup>
- CLINICALLY USED FOR MORE THAN 15 YEARS
- SUPERB SUTURE RETENTION
- HIGH BURST STRENGTH
- COLOUR CODED PACKAGING FOR EASE OF SELECTION

## LifeSpan® ePTFE Vascular Grafts for Vascular Access for Haemodialysis










The LifeSpan ePTFE Vascular Graft selection offers various sizes for the creation of Vascular Access for haemodialysis when other access is not available. It has been recommended that regular / standard wall grafts should be the grafts of choice for the creation of Vascular Access<sup>2</sup>. Center spiral models are designed for vascular access procedures requiring enhanced resistance to kinking and compression in the middle section of the grafts (e.g. narrow loop grafts). Stepped and Quick Tapered grafts are designed to reduce the risk of steal syndrome and high cardiac output. The packaging is colour coded for ease of reference.

	Inner Diameter (ID)	Length (L)	Wall Thickness R = Regular Wall/ Standard Wall T = Thin Wall	Description	Colour Code Packaging	Model # [REF]
 Regular Wall, straight	5 mm	10 cm	R		Yellow	R05010*
	6 mm	10 cm	R		Yellow	R06010
	7 mm	10 cm	R		Yellow	R07010
	8 mm	10 cm	R		Yellow	R08010
	5 mm	20 cm	R		Yellow	R05020*
	6 mm	20 cm	R		Yellow	R06020
	7 mm	20 cm	R		Yellow	R07020
	8 mm	20 cm	R		Yellow	R08020
	6 mm	30 cm	R		Yellow	R06030
	5 mm	50 cm	R		Yellow	R05050*
	6 mm	50 cm	R		Yellow	R06050
	7 mm	50 cm	R		Yellow	R07050
	8 mm	50 cm	R		Yellow	R08050
 Regular Wall, straight, Center Spiral Support	6 mm	40 cm	R	10 cm Center Spiral	Yellow	R06040CS
	6 mm	50 cm	R	5 cm Center Spiral	Yellow	R06050CS5
	6 mm	50 cm	R	10 cm Center Spiral	Yellow	R06050CS
	7 mm	50 cm	R	10 cm Center Spiral	Yellow	R07050CS
	8 mm	50 cm	R	10 cm Center Spiral	Yellow	R08050CS
 Regular Wall, stepped	4-7 mm	50 cm	R		Green	RS47050
 Regular Wall, stepped, Center Spiral Support	4-7 mm	50 cm	R	5 cm Center Spiral	Green	RS4750CS5
	4-7 mm	50 cm	R	10 cm Center Spiral	Green	RS47050CS
 Regular Wall, Quick Taper	4-7 mm	40 cm	R		Grey	QT47040
	4-7 mm	50 cm	R		Grey	QT47050
 Regular Wall, Quick Taper, Center Spiral Support	4-7 mm	45 cm	R	5 cm Center Spiral	Grey	QT4745CS5
	4-7 mm	45 cm	R	10 cm Center Spiral	Grey	QT47045CS

\* products not for sale in the U.S.

# LifeSpan® ePTFE Vascular Grafts for Peripheral Vascular Procedures

The LifeSpan ePTFE Vascular Graft selection also offers various sizes for peripheral reconstructions. Regular/standard wall and thin wall grafts can be used for peripheral vascular reconstructions. Models with full or partial external spiral support are designed for extra-anatomic surgical reconstructions and for reconstructions requiring enhanced resistance to kinking and compression (e.g. axillo-femoral bypass, femoro-femoral bypass, femoro-popliteal or distal bypass). The external spiral support can be removed, facilitating an easy creation of the anastomosis to the vessel. The packaging is colour coded for ease of reference in the operating room.

	Inner Diameter (ID)	Length (L)	Wall Thickness R = Regular Wall/ Standard Wall T = Thin Wall	Description	Colour Code Packaging	Model # [REF]
 Regular Wall, straight	5 mm	10 cm	R		Yellow	R05010*
	6 mm	10 cm	R		Yellow	R06010
	7 mm	10 cm	R		Yellow	R07010
	8 mm	10 cm	R		Yellow	R08010
	5 mm	20 cm	R		Yellow	R05020*
	6 mm	20 cm	R		Yellow	R06020
	7 mm	20 cm	R		Yellow	R07020
	8 mm	20 cm	R		Yellow	R08020
	6 mm	30 cm	R		Yellow	R06030
	5 mm	50 cm	R		Yellow	R05050*
	6 mm	50 cm	R		Yellow	R06050
	7 mm	50 cm	R		Yellow	R07050
	8 mm	50 cm	R		Yellow	R08050
	5 mm	80 cm	R		Yellow	R05080*
	6 mm	80 cm	R		Yellow	R06080
	7 mm	80 cm	R		Yellow	R07080
	8 mm	80 cm	R		Yellow	R08080
10 mm	80 cm	R		Yellow	R10080	
 Thin Wall, straight	5 mm	20 cm	T		Red	T05020*
	6 mm	20 cm	T		Red	T06020
	7 mm	20 cm	T		Red	T07020
	8 mm	20 cm	T		Red	T08020
	5 mm	50 cm	T		Red	T05050*
	6 mm	50 cm	T		Red	T06050
	7 mm	50 cm	T		Red	T07050
	8 mm	50 cm	T		Red	T08050
	5 mm	80 cm	T		Red	T05080*
	6 mm	80 cm	T		Red	T06080
	7 mm	80 cm	T		Red	T07080
	8 mm	80 cm	T		Red	T08080
	10 mm	80 cm	T		Red	T10080
 Regular Wall, straight, Full External Spiral Support	6 mm	50 cm	R	50 cm Spiral Support Length	Yellow	R06050C50
	7 mm	50 cm	R	50 cm Spiral Support Length	Yellow	R07050C50
	8 mm	50 cm	R	50 cm Spiral Support Length	Yellow	R08050C50
	6 mm	80 cm	R	80 cm Spiral Support Length	Yellow	R06080C80
	7 mm	80 cm	R	80 cm Spiral Support Length	Yellow	R07080C80
	8 mm	80 cm	R	80 cm Spiral Support Length	Yellow	R08080C80
10 mm	80 cm	R	80 cm Spiral Support Length	Yellow	R10080C80	
 Thin Wall, straight, External Spiral Support 50/30	6 mm	50 cm	T	30 cm Spiral Support Length	Red	T06050C30
	7 mm	50 cm	T	30 cm Spiral Support Length	Red	T07050C30
	8 mm	50 cm	T	30 cm Spiral Support Length	Red	T08050C30
 Thin Wall, straight, External Spiral Support 80/50	6 mm	80 cm	T	50 cm Spiral Support Length	Red	T06080C50
	7 mm	80 cm	T	50 cm Spiral Support Length	Red	T07080C50
	8 mm	80 cm	T	50 cm Spiral Support Length	Red	T08080C50
 Thin Wall, straight, Full External Spiral Support	6 mm	50 cm	T	50 cm Spiral Support Length	Red	T06050C50
	7 mm	50 cm	T	50 cm Spiral Support Length	Red	T07050C50
	8 mm	50 cm	T	50 cm Spiral Support Length	Red	T08050C50
	6 mm	80 cm	T	80 cm Spiral Support Length	Red	T06080C80
	7 mm	80 cm	T	80 cm Spiral Support Length	Red	T07080C80
	8 mm	80 cm	T	80 cm Spiral Support Length	Red	T08080C80
	10 mm	80 cm	T	80 cm Spiral Support Length	Red	T10080C80
 Thin Wall, Gradual Taper, External Spiral Support	7-4 mm	80 cm	T	70 cm Spiral Support Length	Pink	GT74080C70*
 Regular Wall, Gradual Taper	7-4 mm	70 cm	R		Pink	GR74070*
 Thin Wall, Gradual Taper	7-4 mm	70 cm	T		Pink	GT74070*

\* products not for sale in the U.S.



# LifeSpan® ePTFE Vascular Graft

## EXCELLENT HANDLING AND PROVEN PERFORMANCE<sup>1</sup>

LifeSpan ePTFE Vascular Grafts have been indicated for peripheral vascular reconstructions and Vascular Access for haemodialysis and are used in clinical practice for more than 15 years.

The soft ePTFE material with superb suture retention, high burst strength and excellent handling makes the product an ideal selection as a implant when ePTFE shall be the graft of choice.

A variety of shapes, lengths and diameters provides a good set of options for the surgeon to find the correct implant of choice. The colour coded packaging makes the selection easy in the operating room.

- PERIPHERAL AND VASCULAR ACCESS
- PROVEN PERFORMANCE<sup>1</sup>
- CLINICALLY USED FOR MORE THAN 15 YEARS
- SUPERB SUTURE RETENTION
- HIGH BURST STRENGTH
- COLOUR CODED PACKAGING FOR EASE OF SELECTION

### TECHNICAL DATA:

<b>Material</b>	
Vascular Graft:	ePTFE - expanded PolyTetraFluoroEthylene
External Spiral Support:	PTFE - PolyTetraFluoroEthylene
<b>Wall Thickness (6 mm graft - nominal)</b>	
Regular/Standard Wall:	0,63 mm
Thin Wall:	0,4 mm
<b>Internodal Distance (nominal):</b>	20 +/- 10 µm
<b>Suture Retention Strength:</b>	min. 300 grams
<b>Average (+/- SD) Min. Burst Strength<sup>3</sup>:</b>	218 +/- 31 psi

1) Cinat ME, Hopkins J, Wilson SE.  
A prospective evaluation of PTFE graft patency and surveillance techniques in hemodialysis access. Ann Vasc Surg 1999;13:191-198.  
2) Lenz BJ, Veldenz HC, Dennis JW, et al.  
A three-year follow-up on standard versus thin wall ePTFE grafts for hemodialysis. J Vasc Surg 1998;28:464-470  
3) Data on file

**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**  
Grabenstrasse 25  
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 GK**  
1F Kubodera Twin Tower Bldg.  
2-9-4 Kudan-minami, Chiyoda-ku  
Tokyo 102-0074  
Japan

T +81 (0)3 5215 5681  
F +81 (0)3 5215 5682

**LeMaitre Vascular ULC**  
5915 Airport Road, Suite 608  
Mississauga, Ontario  
Canada L4V 1T1

T +1 905 673 2266 0  
F +1 905 673 2223

**LeMaitre Vascular PTY LTD**  
214/189 South Centre Road  
Tullamarine, VIC 3043  
Australia

T +61 (0) 3 9330 4775  
F +61 (0) 3 9330 4772

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

T +1 781 221 2266  
F +1 781 221 2223

www.lemaitre.com



Your Peripheral Vision™