Certificate US21/819944236

The management system of:

Digitally signed by Captari Alexandru
Date: 2023.03.05 13:22:59 EET
Reason: MoldSign Signature
Location: Moldova

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

UKAS MANAGEMENT SYSTEMS
0005

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

21HC 13485 MS 0721

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

UKAS MANAGEMENT SYSTEMS
0005

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) Ridlerstraβe 65 80339 Munich Germany
Manufacturer: Manufacturer Address:	**LeMaitre Vascular, Inc.** 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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 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:G1 060725 0020 Rev. 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

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

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

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

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

Report no.: 72161580

Valid from: 2021-05-21
Valid until: 2024-05-26

Date, 2021-05-21

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

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

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

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

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

TÜV®

LeMaitre®
2022 EMEA Product Overview

Updated: March 2022

LeMaitre®

XenoSure® Biologic Surgical Patch

4-year Shelf Life

	Width	Length	Model #
XenoSure® Biologic Surgical Patch *(Sterile)* (Bovine Pericardium) **Thickness range 0.350 - 0.750 mm**			
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