DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10000326104-PA-NA-CHN	PRJC-26553-2007-PRC-RGC	27 May 2024

This is to certify that the quality system of:

LifeScience PLUS, Inc.

2520A Wyandotte Street, Mountain View, CA 94043 USA

For design, production and final product inspection/testing of:
ABSORBABLE HAEMOSTATIC DEVICES

Has been assessed with respect to:
THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 20 November 2019

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Cathrine Wisbech

Cathrine Wisbech

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Certificate No.:
10000326104-PA-NA-CHN

Project No.:
PRJC-26553-2007-PRC-RGC

Valid Until:
27 May 2024

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	19 November 2019

Products covered by this Certificate:

Product Description	Product Name	Class
BloodSTOP iX Absorbable Hemostat	Various Sizes: BS-iX14 2"x2" (5cmX5cm) BS-iX15 2"x4" (5cmX10cm) BS-iX16 2"x3" (5cmX7.5cm) BS-iX17 4"x8" (10cmX20cm) BS-iX19 4"x4" (10cmX10cm) BS-iX20 2"x14" (5cmX35cm) BS-iX22 1"x2" (2.5cmX5cm) BS-iX27 0.5"x2" (1.3cmX5cm)	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 10000326028-PA-NA-CHN

Sites covered by this certificate

Site Name	Address
Head Office	2520A Wyandotte Street, Mountain View, CA 94043, USA
Head Office Mailing Address	PO BOX 60783, Palo Alto, CA 94306

EU Representative

Wellkang Ltd, Black Church, St. Mary's Place, Dublin 7, Ireland

Certificate No.:
10000326104-PA-NA-CHN

Project No.:
PRJC-26553-2007-PRC-RGC

Valid Until:
27 May 2024

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

DNV·GL

EC DESIGN

Examination Certificate

Certificate No.:	Project No.:	Valid Until:
10000326028-PA-NA-CHN	PRJC-26553-2007-PRC-RGC	27 May 2024

This is to certify that:

Absorbable Haemostatic Devices

Manufactured by:

LifeScience PLUS, Inc.

2520A Wyandotte Street, Mountain View, CA 94043 USA

Has been assessed with respect to:

EXAMINATION OF THE DESIGN OF THE PRODUCT AS DESCRIBED IN ANNEX II SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 20 November 2019

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Cathrine Wisbech

Cathrine Wisbech

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	19 November 2019

Products covered by this Certificate:

Type of medical device and identification no.:	Medical Device Class:	GMDN code:
BloodSTOP iX Absorbable Hemostat BS-iX14 2"x2" (5cmX5cm) BS-iX15 2"x4" (5cmX10cm) BS-iX16 2"x3" (5cmX7.5cm) BS-iX17 4"x8" (10cmX20cm) BS-iX19 4"x4" (10cmX10cm) BS-iX20 2"x14" (5cmX35cm) BS-iX22 1"x2" (2.5cmX5cm) BS-iX27 0.5"x2" (1.3cmX5cm)	III	38771
Short description of the Medical Device:		
BloodSTOP iX Absorbable Hemostat is a water-soluble hemostatic device made from oxidized etherified regenerated carboxymethylcellulose. Internal use, wholly absorbable, for the control of bleeding during and after surgery, for the general population and for those on anticoagulation medication. Sterilized by Gamma radiation.		

Certificate No.:
10000326028-PA-NA-CHN

Project No.:
PRJC-26553-2007-PRC-RGC

Valid Until:
27 May 2024

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate