LifeScience PLUS
REVOLUTIONARY WOUND CARE

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	LifeScience PLUS, Inc.
Manufacturer address and contact details	2520A Wyandotte Street Mountain View, CA 94043
Single Registration Number (SRN) (if available)	US-MF-000004095
Authorised Representative name (if applicable)	Wellkang Ltd
Authorised Representative address and contact details	Enterprise Hub, NW Business Complex,, BT48 8SE Derry United Kingdom (Northern Ireland only)
Single Registration Number (SRN) (if available)	XI-AR-000001836
Notified body name (if applicable)	BSI Group
Notified body number (if applicable)	2797
Directive Certificate number(s) to which this confirmation is made (if applicable)	10000326104-PA-NA-CHN (Full Quality Assurance); 10000326028-PA-NA-CHN (Design)
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024.05.27
End date of extended validity/transition period	**2027.12.31**

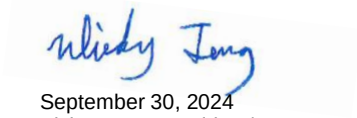
We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and*
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

- **Directive Certificates** as listed above and in the attached schedule
  - Directive Certificates covering the listed devices were issued after 25 May 2017, were valid on 26 May 2021 and have not been withdrawn afterwards.
  - Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made to notified body, BSI, for the devices listed in the attached schedule and a written agreement was signed in accordance with Section 4.3, second subparagraph of Annex VII MDR and made effective 26 September 2024.
- **Quality Management System (QMS)**
  A QMS in accordance with Article 10(9) MDR is in place.
- **Devices as listed in the attached schedule**
  - The devices continue to comply with the MDD.
  - There are no significant changes in the design and intended purpose.
  - The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer, LifeScience PLUS, Inc., Mountain View, CA, 94043, USA:



September 30, 2024
Vicky Feng, President/CEO
vicky.feng@lifescienceplus.com

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[1] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Absorbable Haemostatic Devices	10000326104-PA-NA-CHN; 10000326028-PA-NA-CHN	*May 27, 2024*	*DNV Product Assurance AS, 2460*	BSI Group 2797	December 31, 2027	n/a

LifeSciencePLUS, Inc., 2520A Wyandotte St., Mountain View, CA, 94043, USA
Office 1-650.565.8172, **Fax** 1-650.336.1130
www.lifescienceplus.com

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

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

By Royal Charter

Supplementary information to AR120 814771

Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to:

LifeScience PLUS, Inc.
2520A Wyandotte Street
Mountain View, CA 94043
USA

Date: 23 August 2024

Changes Approved:

Date	Reference Number	Action
23 August 2024	30246754	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Absorbable Haemostatic Devices (BloodSTOP iX Absorbable Hemostat). Original NB Certificate Number: 10000326104-PA-NA-CHN

Inspiring trust for a more resilient world.

23 August 2024

LifeScience PLUS, Inc.
2520A Wyandotte Street
Mountain View, CA 94043
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) (as amended by (EU) 2023/607) and as per the guidance provided in MDCG 2020-3.

The related MDD certificate specified below remains valid until the expiry date stated on the certificate or until the end of the transition period as specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), subject to the manufacturer's continued compliance to the other conditions provided in Article 120(3c) of MDR (as amended by (EU) 2023/607).

Original Certificate Number	**BSI Reference Number**	**Directive and Annex**	**Reference Number**	**Changes approved**
10000326104-PA-NA-CHN	AR120 814771	93/42/EEC Annex II excluding Section 4	30246754	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Absorbable Haemostatic Devices (BloodSTOP iX Absorbable Hemostat). Original NB Certificate Number: 10000326104-PA-NA-CHN

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl

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

Certificate No.:
10000326028-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:

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.		

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

By Royal Charter

Supplementary information to AR120 814772

Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to:

LifeScience PLUS, Inc.
2520A Wyandotte Street
Mountain View, CA 94043
USA

Date: 23 August 2024

Changes Approved:

Date	Reference Number	Action
23 August 2024	30246754	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Absorbable Haemostatic Devices (BloodSTOP iX Absorbable Hemostat). Original NB Certificate Number: 10000326028-PA-NA-CHN

Inspiring trust for a more resilient world.

23 August 2024

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To whom it may concern,

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This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) (as amended by (EU) 2023/607) and as per the guidance provided in MDCG 2020-3.

The related MDD certificate specified below remains valid until the expiry date stated on the certificate or until the end of the transition period as specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), subject to the manufacturer's continued compliance to the other conditions provided in Article 120(3c) of MDR (as amended by (EU) 2023/607).

Original Certificate Number	**BSI Reference Number**	**Directive and Annex**	**Reference Number**	**Changes approved**
10000326028-PA-NA-CHN	AR120 814772	93/42/EEC Annex II Section 4	30246754	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Absorbable Haemostatic Devices (BloodSTOP iX Absorbable Hemostat). Original NB Certificate Number: 10000326028-PA-NA-CHN

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

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