



# EC Certificate

## Full Quality Assurance System

Certificate No.:  
**9936-2017-CE-RGC-NA-PS Rev. 1.0**

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

Valid Until:  
**09 January 2019**

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, 14 September 2018**



For:  
**DNV GL PRESAFE AS**

  
**Tone Kolpus**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://www.presafe.com/digital_signatures) for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.



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### 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	Replace the certificate 3995-2013-CE-RGC-NA 0.0 (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460)	2017-11-22
1.0	Manufacturing site removed from the certificate and reference to Design Exam. Certificate corrected	2018-09-14

Products covered by this Certificate:

Product Description	Product Name	Class
BloodSTOP iX Absorbable Hemostat	Various Sizes: BS-iX14, BS-iX15, BS-iX16, BS-iX17, BS-iX20, BS-iX27	III*

\* Design assessment is covered by a separate EC-Design Examination Certificate No 10626-2017-CE-RGC-NA-PS

### Sites covered by this certificate

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., Suite B, 29 Harley Street, London W1G 9QR, UK



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### 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