EC Design Examination Certificate

Certificate No.:	Project No.:	Valid Until:
10626-2017-CE-RGC-NA-PS	PRJC-26553-2007-PRC-RGC	09 January 2019

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 (Module H1) 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, 22 November 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

Alessandra Rinna

The Certificate has been digitally signed.
See 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.

EC Design-Examination Certificate

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift for 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-D (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460) issued	2017-11-22

Products covered by this Certificate:

Type of medical device and identification no.:	**Medical Device Class:**	**GMDN code:**
BloodSTOP iX Absorbable Hemostat	III	38771
Short description of the Medical Device: BloodSTOP iX Absorbable Hemostat is a water-soluble hemostatic device made from oxidized-etherified regenerated cellulose. 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 change of the products detailed above 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