EC Design Examination Certificate

Certificate No.:	Project No.:	Valid Until:
242606-2017-CE-IND-NA-PS Rev. 0.0	**PRJC-521018-2015-MSL-IND**	**06 July 2020**

This is to certify that:

Sterile Gelatine based Surgical Absorbable Haemostatic Sponge

Manufactured by:

Aegis Lifesciences

215/216, Mahagujarat Industrial Estate-382 213,
Ahmedabad, Gujarat, India

Has been assessed with respect to:

Examination of the design of the product as described in Annex II section 4 (Module B1) 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, 23 August 2017

For:
DNV GL NEMKO PRESAFE AS

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

Villy Rønneberg

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.

Digitally signed by Chitic Ecaterina
Date: 2019.12.19 20:27:59 EET
Reason: MoldSign Signature
Location: Moldova

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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 80067-2010-CE-IND-NA-D (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460) + Brand name addition in Bold	2017-08-23

Products covered by this Certificate:

Type of medical device and identification no.:	**Medical Device Class:**	**GMDN code:**
Sterile gelatine based surgical & wound care absorbable haemostatic sponge	III	
Short description of the Medical Device: "SURGISPON®, MEDISPONGE, UNISPONGE, **BLOXANG, GELASPON, HEMOGEL, HEMOSPONGE, PERISPONGE™, SURGIGEL** are surgical and wound care absorbable haemostatic sponges, manufactured from highly purified first extract grade porcine gelatine material for use in various surgical and wound care procedures, where traditional haemostatic is difficult or impractical and use of other non-absorbable materials is undesirable. It absorbs approximately 40-50 times, its weight of water/blood and adheres easily to the bleeding site. When implanted in vivo, it is completely absorbed within 3-4 weeks. SURGISPON®, MEDISPONGE, UNISPONGE, **BLOXANG, GELASPON, HEMOGEL, HEMOSPONGE, PERISPONGE™, SURGIGEL** gelatine sponges have a porous structure which activates the thrombocytes at the moment blood comes in contact with the matrix of the sponge. This causes the thrombocytes to release a series of substances which promote their aggregation at the same time as their surfaces change character, thus enabling them to act as a catalyst for the formation of the fibrin. Method of sterilization is through 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.

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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