

C2402



EC Certificate Full Quality Assurance System

Certificate No.:
12493-2018-CE-IBE-NA-PS Rev 1.0

Project No.:
PRJC-535822-2015-PRC-ESP

Valid Until:
20 April 2026

This is to certify that the quality system of:

EQUIMEDICAL BV

Zwanenburgerdijk 349
1161 NN Zwanenburg
Netherlands

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

Sterile Haemostatic Absorbable Gelatin Sponges

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.1.a and Annex II (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, 21 April 2021



For:
DNV GL NEMKO PRESAFE AS

Cathrine Wisbech

Cathrine Wisbech

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 Certificate

Full Quality Assurance System

Certificate No.:
12493-2018-CE-IBE-NA-PS Rev 1.0

Project No.:
PRJC-535822-2015-PRC-ESP

Valid Until:
20 April 2026

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	2018-05-28
1.0	Original Certificate	2021-04-21

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Haemostatic Absorbable Gelatin Sponges	Equispon	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 12492-2018-CE-IBE-NA-PS Rev 1.0

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
EQUIMEDICAL HAEMOSTATS, S.L.	Calle Gaudi 14, 29680, Estepona, Spain

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Certificate No.:
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Project No.:
PRJC-535822-2015-PRC-ESP

Valid Until:
20 April 2026

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



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EC Design Examination Certificate

Certificate No.:
12492-2018-CE-IBE-NA-PS Rev 1.0

Project No.:
PRJC-535822-2015-PRC-ESP

Valid Until:
20 April 2026

This is to certify that:

Sterile Haemostatic Absorbable Gelatin Sponges

Manufactured by:

EQUIMEDICAL BV

Zwanenburgerdijk 349
1161 NN Zwanenburg
Netherlands

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, 21 April 2021



For:
DNV GL NEMKO PRESAFE AS

Cathrine Wisbech

Cathrine Wisbech

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See www.presafe.com/digital_signatures for more info

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EC Design Examination Certificate

Certificate No.: 12492-2018-CE-IBE-NA-PS Rev 1.0

Project No.: PRJC-535822-2015-PRC-ESP

Valid Until: 20 April 2026

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	2018-05-28
1.0	Original Certificate	2021-04-21

Products covered by this Certificate:

Type of medical device and identification no.: Sterile Haemostatic Absorbable Gelatin Sponges Model Names: EQUISPON	Medical Device Class: III	GMDN code: 48170
Short description of the Medical Device: Sterile Haemostatic Absorbable Gelatin Sponge – It is a sterile absorbable gelatin hemostatic sponge, manufactured from highly purified neutral gelatin material of porcine origin. It is white, water-insoluble, highly porous, pliable product intended for application to bleeding surfaces as a hemostat. The uniform porosity of EQUISPON® guarantees favorable hemostasis. It adheres well to the bleeding site and absorbs approximately 40-50 times its own weight and assists in achieving hemostasis in 3 to 6 minutes. The entire content of pack is sterilized by gamma irradiation.		

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

