Presafe®
A DNV GL & NEMKO COMPANY

Management System Certificate

Certificate No.:	Project No.:	Initial certification date:	Valid until:
277179-2019-AQ-IBE-NA-PS-Rev1.0	PRJC-606469-2019-MSC-ESP	28 February 2019	27 February 2024

This is to certify that the management system of:

Equimedical B.V

Zwanenburgerdijk 349
1161 NN Zwanenburg
Netherlands

Complies with the requirements of:

ISO 13485:2003/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Design, Manufacturing and Wholesale of Oxidized Regenerated Cellulose (Equicel and Equitamp), Bone Wax (Equiwax), Absorbable Gelatin Sponge (Equispon), Internal Surgical Glue (Equicel) and Absorbable Adhesion Barries (Equitamp).

Place and date:
Høvik, 28 February 2019

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL NEMKO PRESAFE AS

Eugenie Winger Husebye

Eugenie Winger Husebye

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.

/

This is a copy of a document which has been shown to me,
mr. Ronaldus Henricus Sengers, civil law notary, residing at
Haarlemmermeer, the Netherlands, today, the 29th of October 2019

mr. R.H. SENGERS
Notaris te HAARLEMMERMEER

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. País: Los Países Bajos
   El presente documento público
2. ha sido firmado por **dhr. R.H. Sengers**
3. quien actúa en calidad de notario en Haarlemmermeer
4. y está revestido del sello/timbre del susodicho notario

Certificado

5. en Haarlem
6. el día 30-10-2019
7. por el Secretario Judicial del Tribunal de Distrito Noord-Holland
8. bajo el número: 19/3041-63
9. Sello/timbre:
10. Firma:

H.T. Sepp - Valpoort

EC Certificate
Full Quality Assurance System

Certificate No.: **11152-2017-CE-IBE-NA-PS Rev. 1.0**

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

Valid Until: **04 April 2023**

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:

Oxidized regenerated cellulose

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, 22 May 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

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

A DNV GL & NEMKO COMPANY

Certificate No.: **11152-2017-CE-IBE-NA-PS Rev. 1.0**

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

Valid Until: **04 April 2023**

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	2018-04-04
1.0	Address change	2018-05-22

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Absorbable Oxidised Regenerated Cellulose	• Equicel • Equitamp	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 11150- 2017-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

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
11152-2017-CE-IBE-NA-PS Rev. 1.0	**PRJC-535822-2015-PRC-ESP**	**04 April 2023**

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

EC Design Examination Certificate

A DNV GL & NEMKO COMPANY

Certificate No.: **11150-2017-CE-IBE-NA-PS Rev. 1.0**

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

Valid Until: **04 April 2023**

This is to certify that:

Oxidized regenerated cellulose

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, 22 May 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

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 Design Examination Certificate

A DNV GL & NEMKO COMPANY

Certificate No.: **11150-2017-CE-IBE-NA-PS Rev 1.0**

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

Valid Until: **04 April 2023**

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	2018-04-04
1.0	Address change	2018-05-22

Products covered by this Certificate:

Type of medical device and identification no.:	**Medical Device Class:**	**GMDN code:**
Equicel and Equitamp (Sterile Absorbable Oxidised Regenerated Cellulose)	III	38771

Short description of the Medical Device:
Equicel and Equitamp are a sterile absorbable oxidized regenerated cellulose, manufactured from highly purified cotton (Equicel) / viscose (Equitamp). It is a pliable product intended for application to bleeding surfaces as a hemostat. Both the products are prepared by oxidising a suitable form of cellulose, cotton (Equicel) / viscose (Equitamp). This is followed by additional processes in order to obtain a pure and high-quality form of oxidised and regenerated cellulose. It is strong and although a slight discoloration may occur with age, this does not affect performance. Equicel / Equitamp is double sterile packed.

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

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.: **12493-2018-CE-IBE-NA-PS**

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

Valid Until: **28 May 2023**

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, 28 May 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

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**
Project No.: **PRJC-535822-2015-PRC-ESP**
Valid Until: **28 May 2023**

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
	Original Certificate	2018-05-28

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

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

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
12493-2018-CE-IBE-NA-PS	**PRJC-535822-2015-PRC-ESP**	**28 May 2023**

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

EC Design Examination Certificate

Certificate No.: **12492-2018-CE-IBE-NA-PS**

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

Valid Until: **28 May 2023**

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, 01 June 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

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 Design Examination Certificate

A DNV GL & NEMKO COMPANY

Certificate No.: **12492-2018-CE-IBE-NA-PS**

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

Valid Until: **28 May 2023**

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
	Original Certificate	2018-05-28

Products covered by this Certificate:

Type of medical device and identification no.:	**Medical Device Class:**	**GMDN code:**
Sterile Haemostatic Absorbable Gelatin Sponges **Model Names:** EQUISPON	III	NA
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

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
12501-2018-CE-IBE-NA-PS	**PRJC-535822-2015-PRC-ESP**	**28 May 2023**

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:

Bone Wax

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, 28 May 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

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.:	Project No.:	Valid Until:
12501-2018-CE-IBE-NA-PS	**PRJC-535822-2015-PRC-ESP**	**28 May 2023**

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
	Original Certificate	2018-05-28

Products covered by this Certificate:

Product Description	Product Name	Class
Bone Wax	Equiwax	IIb

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

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
12501-2018-CE-IBE-NA-PS	**PRJC-535822-2015-PRC-ESP**	**28 May 2023**

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

Presafe®
A DNV GL & NEMKO COMPANY

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
12497-2018-CE-IBE-NA-PS	**PRJC-535822-2015-PRC-ESP**	**28 May 2023**

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:

Internal Surgical Glue

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, 28 May 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

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.: **12497-2018-CE-IBE-NA-PS**
Project No.: **PRJC-535822-2015-PRC-ESP**
Valid Until: **28 May 2023**

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
	Original Certificate	2018-05-28

Products covered by this Certificate:

Product Description	Product Name	Class
Internal Surgical Glue	Equicel	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 12496-2018-CE-IBE-NA-PS

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

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
12497-2018-CE-IBE-NA-PS	**PRJC-535822-2015-PRC-ESP**	**28 May 2023**

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

EC Design Examination Certificate

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
12496-2018-CE-IBE-NA-PS	**PRJC-535822-2015-PRC-ESP**	**28 May 2023**

This is to certify that:

Internal Surgical Glue

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, 01 June 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

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 Design Examination Certificate

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
12496-2018-CE-IBE-NA-PS	**PRJC-535822-2015-PRC-ESP**	**28 May 2023**

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
	Original Certificate	2018-05-28

Products covered by this Certificate:

Type of medical device and identification no.:	**Medical Device Class:**	**GMDN code:**
Internal Surgical Glue **Model Names:** EQUICEL	III	NA
Short description of the Medical Device: Equicel Internal Surgical Glue is is a synthetic biodegradable cyanoacrylate basis glue. It has high adhesive and haemostatic properties and once it is polymerised it creates an efficient antiseptic barrier against the most diffused infective or pathogenic agents during the surgical intervention. Equicel Internal Surgical Glue polymerises quickly in contact with live tissue and wet environment creating a thin and elastic film having high tensile properties which guarantee strong adhesion to the tissues. This film naturally conforms with the tissues on which it was applied; it is not permeable to liquids and is not altered by blood or organic liquids. Equicel Internal Surgical Glue is indicated for use as an adjunct to standard methods of surgical repair (such as sutures, staples, electrocautery, and/or patches) to bond, seal, and/or reinforce soft tissue.		

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

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
12495-2018-CE-IBE-NA-PS	**PRJC-535822-2015-PRC-ESP**	**28 May 2023**

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:

Absorbable Adhesion Barrier (Oxidized Regenerated Cellulose)

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, 28 May 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

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.: **12495 2018-CE-IBE-NA-PS**
Project No.: **PRJC-535822-2015-PRC-ESP**
Valid Until: **28 May 2023**

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
	Original Certificate	2018-05-28

Products covered by this Certificate:

Product Description	Product Name	Class
Absorbable Adhesion Barrier (ORC)	Equitamp	III*

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 12494-2018-CE-IBE-NA-PS

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

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
12495-2018-CE-IBE-NA-PS	**PRJC-535822-2015-PRC-ESP**	**28 May 2023**

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

EC Design Examination Certificate

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
12494-2018-CE-IBE-NA-PS	**PRJC-535822-2015-PRC-ESP**	**28 May 2023**

This is to certify that:

Absorbable Adhesion Barrier (Oxidized Regenerated Cellulose)

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, 01 June 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

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 Design Examination Certificate

A DNV GL & NEMKO COMPANY

Certificate No.: **12494-2018-CE-IBE-NA-PS**

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

Valid Until: **28 May 2023**

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
	Original Certificate	2018-05-28

Products covered by this Certificate:

Type of medical device and identification no.:	**Medical Device Class:**	**GMDN code:**
Absorbable Adhesion Barrier (Oxidized Regenerated Cellullose) **Model Names:** EQUITAMP	III	NA

Short description of the Medical Device:
Equitamp Absorbable Adhesion Barrier (Oxidized Regenerated Cellulose) is a sterile absorbable off-white knitted fabric prepared by the controlled oxidation of regenerated cellulose. It reduces adhesion formation in gynecologic pelvic surgery by being applied dry to traumatized surfaces after meticulous hemostasis consistent with microsurgical principles to physically separate apposing tissue surfaces during the period of reperitonealization. When used as directed, it is easy to apply and is absorbed from the site of implantation within four weeks. Absorption rate depends upon several factors including the amount used and implantation site. It is chemically composed of oxidized regenerated cellulose which has been shown not to enhance bacterial growth. It is indicated as an adjuvant in open (laparotomy) gynecologic pelvic surgery for reducing the incidence of postoperative pelvic adhesions after meticulous hemostasis is achieved consistent with microsurgical principles.

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

Presafe®
A DNV GL & NEMKO COMPANY

Management System Certificate

Certificate No.:	Project No.:	Initial certification date:	Valid until:
277179-2019-AQ-IBE-NA-PS-Rev1.0	PRJC-606469-2019-MSC-ESP	28 February 2019	27 February 2024

This is to certify that the management system of:

Equimedical B.V

Zwanenburgerdijk 349
1161 NN Zwanenburg
Netherlands

Complies with the requirements of:

ISO 13485:2003/NS-EN ISO 13485:2016

The Certificate is valid for the following scope:

Design, Manufacturing and Wholesale of Oxidized Regenerated Cellulose (Equicel and Equitamp), Bone Wax (Equiwax), Absorbable Gelatin Sponge (Equispon), Internal Surgical Glue (Equicel) and Absorbable Adhesion Barries (Equitamp).

Place and date:
Høvik, 28 February 2019

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL NEMKO PRESAFE AS

Eugenie Winger Husebye

Eugenie Winger Husebye

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.