DemeTECH®

"A Trusted Name In Medicine"

Agosto 4, 2022

Certificación de buenas prácticas de fabricación (GMP)

Como funcionario responsable de DemeTech, por la presente certifico que la compañía y todos los productos que se fabrican en la misma, continúan siendo , a mi leal saber, y entender, conforme a la Ley Federal Food, Drug, and Cosmetic Act, o las regulaciones pertinentes aplicadas por el U.S. Food and Drug Administration.

Tracy Chadwrick
Director, Calidad y Asuntos Regulatorios

5980 Miami Lakes Drive, Miami Lakes, FL 33014 •
USA Tel: (305) 824-1048 • Fax: (305) 437-7607
Web: www.demetech.us • Email info@demetech.us

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 5959-3-2022

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

Name of Manufacturer
DEMETECH CORP.
5980 Miami Lakes Drive
Miami Lakes, FL USA 33014

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from March 08, 2022 to March 07, 2024.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
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Certificate No. 5959-3-2022

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Manufacturer

DEMETECH CORP.
5980 Miami Lakes Drive
Miami Lakes, FL
USA 33014

Name of Product(s)

DemeSILK - Silk Nonabsorbable Suture
DemeLON - Nylon Nonabsorbable Suture
DemeBOND - Polyester Nonabsorbable Suture
DemeLENE - Polypropylene Nonabsorbable Suture
DemeSORB - Absorbable Polyglycolic PGA Suture
DemeGUT Plain - Absorbable Plain Catgut Suture
DemeGUT Chromic - Absorbable Chromic Catgut Suture
DemeDIOX - Absorbable Polydioxanone Surgical Suture
DemeCAPRONE - Absorbable Poliglecaprone 25 Surgical Suture
DemeCRYL - Absorbable Poly(glycolic/L -lactide) PGLA Suture
DemeQUICK - Absorbable Poly(glycolic/L -lactide) PGLA Suture
DemeSTEEL - Nonabsorbable Stainless Steel Surgical Suture
DemeLENE MESH - Mesh Surgical Polymeric
DemeDIOX with Novathreads - Absorbable Polydioxanone Surgical Suture
DemeTECH PTFE - Polytetrafluoroethylene Nonabsorbable Suture
DemeDAC - Polyester Nonabsorbable Suture
DemeFORCE - UHMWPE Nonabsorbable Suture
DemeDIOX Barbed - Absorbable Polydioxanone Surgical Suture
DemeDIOX Barbed with Novathreads - Absorbable Polydioxanone Surgical Suture
DemeMASK - Surgical Mask
DemeMASK - N95 Respirator
SutureGard Suture Retention Device
HemiGard Adhesive Suture Retention Device
SMARTLOOPS - Polyester Nonabsorbable Suture
----------END OF PRODUCT LIST----------

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

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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.

Nit.: 900.155.278-0
Dirección.: Cr. 106 No. 15a-25 Bod. 16 Mnz. 9
Teléfono.: 7561637
Mail: logicall@logicall.com.co
Bogotá D.C., Colombia, Suramérica.

Bogotá D.C., 15 de marzo de 2023

A QUIEN PUEDA INTERESAR

De la manera más atenta me dirijo a ustedes, para certificar que la compañía **ARPA MEDICAL SAS**, con NIT. 900.879.954-9, sostiene relaciones comerciales con nuestra empresa y está certificado ante el INVIMA desde Octubre del 2015 como su operador logístico autorizado en el Certificado de Capacidad de Almacenamiento y/o Acondicionamiento (CCAA), para llevar a cabo procesos de recepción, inspección, acondicionamiento, almacenamiento, alistamiento y Distribución de Dispositivos Médicos, teniendo en cuenta las especificaciones del producto en conformidad con las instrucciones proporcionadas por la Dirección Técnica de **ARPA MEDICAL SAS.**

Adicionalmente certificamos que LOGICALL S.A. cumple con Buenas Prácticas de Manufactura bajo las regulaciones del INVIMA, Actas de la Secretaria de salud (Como Operador Logístico y al Vehículo de trasportadores de productos farmacéuticos y Dispositivos médicos) con concepto favorable y un Sistema de Gestión de Calidad vigente.

Constancia que se expide a petición del interesado en Bogotá a los 15 días del mes de marzo del 2023.

Sin otro en particular,

Atentamente,

LOGICALL LOGISTICA INTEGRADA NIT. 900.155.278-0

NESTOR RAUL OSORIO RODRIGUEZ
Gerente de General
LOGICALL S. A.

V. CONCEPTO TÉCNICO

Una vez evaluado el cumplimiento de los requerimientos previstos en la Serie de Informes Técnicos de la OMS Anexo 4 del informe Técnico 37 y anexo 6 del informe 45: adoptada mediante Resolución 1160 de 2016 del Ministerio de Salud y Protección Social con sus respectivos anexos vigentes, Resolución 3028 de agosto de 2008, Decreto 2086 de junio de 2010 del Ministerio de la Protección Social y Decreto 335 de 2022 del Ministerio de Salud y Protección Social, el grupo de inspección del Instituto Nacional de Vigilancia de Medicamentos y Alimentos - Invima, adscrito al Ministerio de Salud y Protección Social de la República de Colombia, conceptúa que **LOGICALL S.A.,** ubicado en la carrera 106 No. 15 A – 25, Manzana 9, Bodega 16 - Zona Franca de Fontibón- Bogotá D.C, **CUMPLE** con las **BUENAS PRÁCTICAS DE MANUFACTURA FARMACÉUTICA**, por lo tanto, se **RENUEVA** el concepto técnico, para el proceso de acondicionamiento secundario (etiquetado, desetiquetado, estuchado, desestuchado, codificado, colocación de stickers, etiquetas, sellos de seguridad e insertos) de medicamentos estériles y no estériles con base en principios activos comunes y que requieren áreas especiales de manufactura en todas las formas farmacéuticas, que requieran y no requieran cadena de frio.

y se **AMPLIA** la capacidad instalada en áreas (2 líneas) para el proceso de acondicionamiento secundario (etiquetado, desetiquetado, estuchado, desestuchado, colocación de stickers, etiquetas, sellos de seguridad e insertos) de medicamentos estériles y no estériles con base en principios activos comunes y que requieren áreas especiales de manufactura en todas las formas farmacéuticas, que requieran y no requieran cadena de frio.

NOTAS ACLARATORIAS:

1. **COMUNES:** Son principios activos no antibióticos (betalactámicos y no betalactámicos), no sustancias endocrinas de tipo sexual (andrógenos y estrógenos) y sus precursores, no hormonales no sexuales, no antineoplásicos, no inmunosupresores, no radio fármacos y no biológicos.

2. Los medicamentos que requieren áreas especiales de manufactura son los que contienen principios activos antibióticos betalactámicos, sustancias endocrinas de tipo sexual (andrógenos y estrógenos) y sus precursores, antineoplásicos, inmunosupresores y biológicos.
3. El anterior concepto técnico, autoriza únicamente los procesos de acondicionamiento secundario de los medicamento con los principios activos y las formas farmacéuticas anteriormente descritas, que requieren y no requieren cadena de frio.
4. Todo cambio crítico que se haga y afecte las condiciones evaluadas y certificadas durante la presente auditoria, respecto a equipos, áreas, procesos productivos, personal técnico principal (Director Técnico) o de las empresas con las que se contrató la realización de actividades de producción y control de calidad, deberán ser notificados al Invima con el fin de que éste evalúe y verifique si se requiere una visita de ampliación o verificación del concepto técnico emitido, de acuerdo con las disposiciones de la Normatividad Sanitaria correspondiente, so pena de las acciones a que haya lugar.

NOTA:
Se informa al personal del establecimiento **LOGICALL S.A.**, que en cumplimiento de lo establecido en el Artículo 9° del Decreto 335 de 2022, en los próximos 15 días calendario se emitirá la resolución que concede la renovación y ampliación de la certificación de las Buenas Prácticas de Manufactura Farmacéutica, para lo cual se indica que a partir de la semana del 06 de febrero del año 2023 se realizará la notificación de la resolución respectiva utilizando los medios telemáticos habilitados para este fin. Se autoriza expresamente a la Autoridad Sanitaria para realizar la notificación electrónica de la Resolución que consigna el concepto técnico emitido a los correos electrónicos: simon.hernandez@logicall.com.co y nestor.osorio@logicall.com.co

La presente diligencia fue realizada por los suscritos profesionales, conforme a la normatividad sanitaria vigente y sin incurrir en extralimitación de funciones. Para constancia se lee y se hace intercambio de firmas el día 19 de enero de 2023 y cada una de las partes que suscriben esta acta conserva una copia.

Por **INVIMA:**

SANDRA EYICED OYUELA MORENO
Profesional Universitario

MANUEL N. BECERRA MOJICA
Profesional Universitario

Por LOGICALL S.A,

NESTOR OSORIO RODRIGUEZ
Gerente General

SIMON HERNANDEZ SANCHEZ
Gerente de Calidad – Director Técnico

OSCAR MORALES MORALES
Gerente de Producción