Circular Informativa

N.º 073/CD/550.20.001

Data: 28/07/2023

Assunto: **Certificados de Conformidade Falsos – Fabricante EQUIMEDICAL B.V.**

Para: Divulgação geral

Contacto: Centro de Informação do Medicamento e dos Produtos de Saúde (CIMI); Tel. 21 798 7373; E-mail: cimi@infarmed.pt; Linha do Medicamento: 800 222 444

O INFARMED, I.P. teve conhecimento da falsificação dos seguintes certificados CE de conformidade, com data de emissão a 21-04-2021 e data de validade a 20-04-2026, relativos aos dispositivos *esponjas hemostáticas absorvíveis* do fabricante **EQUIMEDICAL B.V.** (anexos I a IV):

N.º do Certificado Falsificado	Dispositivo	Modelo(s)
12493-2018-CE-IBE-NA-PS **Rev 1.0**	*Sterile Haemostatic Absorbable Gelatin Sponges*	Equispon
12492-2018-CE-IBE-NA-PS **Rev 1.0**	*Sterile Haemostatic Absorbable Gelatin Sponges*	Equispon
11152-2017-CE-IBE-NA-PS **Rev. 2.0**	*Oxidized regenerated cellulose*	Equicel Equitamp
11150-2017-CE-IBE-NA-PS **Rev. 2.0**	*Oxidized regenerated cellulose*	Equicel Equitamp

O Organismo Notificado DNV Product Assurance AS (2460) informou não ter emitidos estes certificados ao referido fabricante, e que os mesmos se tratam de falsificações dos certificados que foram suspensos a 24 de maio de 2019 e retirados a 11 de setembro de 2019:

- 12493-2018-CE-IBE-NA-PS **Rev. 0.0**
- 12492-2018-CE-IBE-NA-PS **Rev. 0.0**
- 11152-2017-CE-IBE-NA-PS **Rev. 1.0**
- 11150-2017-CE-IBE-NA-PS **Rev. 1.0**

Em Portugal, à data, não foram identificados registos de dispositivos do fabricante EQUIMEDICAL B.V. que estejam a ser comercializados no mercado nacional, mas, atendendo a que existe livre circulação de produtos no Espaço Económico Europeu, o Infarmed recomenda que os dispositivos Equispon,

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Equicel e Equitamp que ostentem marcação CE 2460 e cuja data de fabrico seja posterior a maio de 2019 e respetivo prazo de validade posterior a maio 2024, não sejam adquiridos nem utilizados.

A deteção, em Portugal, destes dispositivos deve ser reportada à Direção de Produtos de Saúde do Infarmed através dos contactos: tel.: +351 21 798 72 35; *e-mail*: daps@infarmed.pt.

A Vogal do Conselho Diretivo

Erica Rodrigues Viegas

Assinado de forma digital por Erica Rodrigues Viegas
Dados: 2023.07.28 12:25:39 +01'00'

(Erica Viegas)

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Anexo I – Certificado N.º 12493-2018-CE-IBE-NA-PS Rev 1.0

Presafe
A DNV GL & NEMKO COMPANY

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
12493-2018-CE-IBE-NA-PS Rev 1.0	PRJC-535822-2015-PRC-ESP	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

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL NEMKO PRESAFE AS

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.

MSD-CO-075 DNV GL NEMKO PRESAFE AS - Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA Page 1 of 3

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Presafe
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EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
12493-2018-CE-IBE-NA-PS Rev 1.0	PRJC-535822-2015-PRC-ESP	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

Anexo II – Certificado N.º 12492-2018-CE-IBE-NA-PS Rev 1.0

Presafe
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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

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.

MSD-CA-0078 DNV GL NEMKO PRESAFE AS – Veritasveien 3, N-1363 Høvik, Norway – Registered Enterprise No: NO 997 067 401 MVA Page 1 of 2

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Presafe
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EC Design Examination Certificate

Certificate No.: 12492-2018-CE-IRE-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.:	Medical Device Class:	GMDN code:
Sterile Haemostatic Absorbable Gelatin Sponges **Model Names:** EQUISPON	III	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

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Anexo III – Certificado N.º 11152-2017-CE-IBE-NA-PS Rev. 2.0

Presafe
A DNV GL & NEMKO COMPANY

EC Certificate
Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
11152-2017-CE-IBE-NA-PS Rev. 2.0	PRJC-535822-2015-PRC-ESP	21 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:

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, 21 April 2021

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.

MSD-CO-078 DNV GL NEMKO PRESAFE AS - Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA Page 1 of 3

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EC Certificate
Full Quality Assurance System

Certificate No.: **11152-2017-CE-IBE-NA-PS Rev. 2.0**
Project No.: **PRJC-535822-2015-PRC-ESP**
Valid Until: **21 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	2018-04-04
1.0	Address change	2018-05-22
2.0	Original Certificate	2021-04-21

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. 2.0

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

Anexo IV – Certificado N.º 11150-2017-CE-IBE-NA-PS Rev. 2.0

Presafe
A DNV GL & NEMKO COMPANY

EC Design Examination Certificate

Certificate No.: **11150-2017-CE-IBE-NA-PS Rev. 2.0**
Project No.: **PRJC-535822-2015-PRC-ESP**
Valid Until: **20 April 2026**

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, 21 April 2021

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.

MSD-CO-078 DNV GL NEMKO PRESAFE AS - Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 057 401 MVA Page 1 of 2

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Presafe
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EC Design Examination Certificate

Certificate No.: **11150-2017-CE-IBE-NA-PS Rev 2.0**
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	2018-04-04
1.0	Address change	2018-05-22
2.0	Original Certificate	2021-04-21

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