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.

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	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