



# EC Design Examination Certificate

Certificate No.:  
**11522-2017-CE-POL-NA-PS Rev. 0.0**

Project No.:  
**PRJC-287124-2011-PRC-POL**

Valid Until:  
**16 July 2018**

This is to certify that:

**Haemostatic dressing for first aid and treatment of traumatic wounds**

Manufactured by:

**TRICOMED S.A.**

ul. Świętojańska 5/9  
93-493 Łódź  
Poland

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, 15 November 2017**



For:  
**DNV GL NEMKO PRESAFE AS**

**Alessandra Rinna**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://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	Replaces the Certificate 3189-2013-CE-POL-NA-D (NB 0434), following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	2017-11-15

Products covered by this Certificate:

<b>Type of medical device and identification no.:</b> Tromboguard® - haemostatic dressing for first aid and treatment of traumatic wounds	<b>Medical Device Class:</b> III	<b>GMDN code:</b> 11315
<b>Short description of the Medical Device:</b> <b>Haemostatic dressing for first aid and treatment of traumatic wounds - TROMBOGUARD®</b> is a sterile, haemostatic dressing consisting of: <ul style="list-style-type: none"> <li>• hydrophilic polyurethane foam – providing optimal moist wound healing environment and effective fluids management thanks to particular, ‘pore in pore’ structure;</li> <li>• polyurethane film - semi-permeable, external layer protecting the wound from external agents;</li> <li>• active layer consisting of chitosan, alginates and silver salts.</li> </ul> TROMBOGUARD® dressing presents clinically documented haemostatic properties. Silver ions present in the active layer have antimicrobial activity in the structure of the dressing, i.e. protect against bacterial growth inside the dressing.		

## 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