

DECLARATION OF CONFORMITY



Manufacturer: TRICOMED S.A.

Address of the manufacturer: 93-493 Łódź, Poland, 5/9 Świętojańska Street

Product: TROMBOGUARD® haemostatic dressing for first aid and treatment of traumatic wounds

Types/models/versions: Available in sizes Tromboguard®: 5cm x 5cm, 5cm x 10cm, 10cm x 10cm, 10cm x 15cm, 10cm x 20cm, 10cm x 30cm, 10cm x 35cm, 15cm x 15cm, 15cm x 20cm, 20cm x 20cm, 25cm x 25cm, 25cm x 30cm, 25cm x 35cm, 30cm x 30cm, 30cm x 35cm, 35cm x 40cm, 35cm x 50cm, 40cm x 40cm

Class of the product: III

Expiry date: 5 years

Scope: The device stipulated in this declaration is compliant with essential requirements of Annex I of Directive 93/42/EEC and essential requirements of Health Minister Decree dated 17th February 2016 as for essential requirements and compliance evaluation procedure for medical devices.

Notified Body Fulfilment of requirements from Annex I of Directive 93/42/EEC has been confirmed by DNV GL Nemko Presafe AS Notified Body No. 2460, certificate number 11521-2017-CE-POL-NA-PS according to Annex II of the above quoted Directive.

Device stipulated in this declaration is compliant with the following harmonized standards:

| | | |
|----------------------|------------------------|------------------------|
| PN-EN ISO 13485:2012 | PN-EN ISO 11607-1:2011 | PN-EN ISO 14971:2012 |
| PN-EN 1041+A1:2013 | PN-EN ISO 10993-1:2010 | PN-EN ISO 11137-1:2015 |

TRICOMED S.A. holds certified Quality Management System, compliant with requirements of standard ISO 13485:2003 – certificate number: 210116-2016-AQ-POL-FINAS

We hereby declare with full responsibility that manufactured device to which this declaration refers is compliant with reference documents.

Łódź, 16.11.2017 r.

Witold Sujka

The President of the Board

TRICOMED S.A.
PREZES ZARZADU
Dr inż. Witold Sujka