

DECLARATION OF CONFORMITY



Manufacturer: TRICOMED S.A.
Address of the manufacturer: 93-493 Łódź, Poland, 5/9 Świętojańska Street
Product: DALLOP[®] NM Urological tape for surgical treatment of effort incontinence in women
Types/models/versions: Available lengths: 450 mm, MA-271-TNMS-004
600 mm, MA-271-TNMS-003
Class of the product: II b
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 the Notified Body DNV 0434, certificate number 2408-2013-CE-POL-NA Rev. 2.0 according to Annex II of the above quoted Directive.

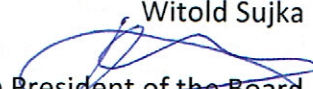
Device stipulated in this declaration is compliant with the following harmonized standards:

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

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, 07.01.2017 r.

Witold Sujka

The President of the Board