DECLARATION OF CONFORMITY

CE 1434

TRICOMED

Manufacturer:	**TRICOMED S.A.**
Address of the manufacturer:	**93-493 Łódź, Poland, 5/9 Świętojańska Street**
Product:	**DALLOP® NM ULTRALIGHT** Urological tape for surgical treatment of effort incontinence in women
Types/models/versions:	Available lengths: 30 cm, 45 cm
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 Polish Center For Testing and Certification, 1434, dated 10th March 2017, certificate number 1434-MDD-27/2017 according to Annex II of the above quoted Directive.

Device stipulated in this declaration is compliant with the following 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	PN-EN ISO 15223-1:2012

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, 13.03.2017 r.

Witold Sujka

The President of the Board