DECLARATION OF CONFORMITY

CE 2460

TRICOMED

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 DNV GL Nemko Presafe AS Notified Body No. 2460, certificate number 11515-2017-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 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, 16.11.2017 r.

Witold Sujka

The President of the Board

TRICOMED S.A.
PREZES ZARZĄDU
dr inż. Witold Sujka