

DECLARATION OF CONFORMITY



Manufacturer: TRICOMED S.A.
Address of the manufacturer: 93-493 Łódź, Poland, 5/9 Świętojańska Street
Product: **APPLICATORS** - Auxiliary instruments for surgical treatment of women urinary incontinence.
Type/model/version: *according to the appendix*
Class of the product: I
Scope: The devices stipulated in this declaration are compliant with essential requirements of Annex I and requirements as concerns declaration of conformity of Annex VII 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.

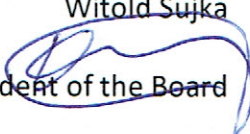
Devices stipulated in this declaration are compliant with the following harmonized standards:

PN-EN ISO 10993-1:2010
PN-EN 1041+A1:2013
PN-EN ISO 13485:2012
PN-EN ISO 16061:2015

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, 07.01.2017 r.

Witold Sujka

The President of the Board

Annex to the Declaration of Conformity of Applicators: List of the products

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TRICOMED

Annex to the Declaration of Conformity of Applicators

LIST OF THE PRODUCTS

APPLICATORS - Auxiliary instruments for surgical treatment of women urinary incontinence.

NO	NAME OF THE PRODUCT	INDEX
1.	TOT Applicator	MA-292-XTOT-001
2.	TVT Applicator	MA-292-XTVT-001
3.	Set of applicators for TOT	MA-292-ZTOT-003
4.	Set of applicators for TOT outside-in	MA-292-ZTOT-004

Łódź, 07.01.2017 r.

Witold Sujka

President of the Board