

# DECLARATION OF CONFORMITY



**Manufacturer:** TRICOMED S.A.  
**Address of the manufacturer:** 93-493 Łódź, Poland, 5/9 Świętojańska Street  
**Product:** CODUBIX® - RIBS  
Prosthesis for filling of extensive defects in the chest wall  
**Types/models/versions:** Available in sizes:  
RZ1 (250x20 mm), MA-272-KOZE-001  
RZ2 (250x200 mm), MA-272-KOZE-002  
**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 17<sup>th</sup> 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

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*