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 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


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