

DECLARATION OF CONFORMITY



Manufacturer: TRICOMED S.A.
Address of the manufacturer: 93-493 Łódź, Poland, 5/9 Świętojańska Street
Product: CODUBIX® ORBITAL WALL 3D Prosthesis of orbital wall
Types/models/versions: Available in size: (S, L, M)P, (S, L, M)L.

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 ISO 14971:2012	PN-EN ISO 10993:1-2010
PN-EN ISO 15223-1:2012	PN-EN ISO 17665-1:2008	PN-EN 1041+A1:2013

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