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.


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


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