DECLARATION OF CONFORMITY

MANUFACTURER:

Company
Osteogenics Biomedical, Inc.
4620 71st St. Bldg. 78-79
Lubbock, TX, 79424, United States

Representative
Ms. Jessica Cedillo
Regulatory Affairs Associate

EUROPEAN REPRESENTATIVE:

Company Name
Emergo Europe

Address
Prinsessegracht 20
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PRODUCT:

Product Name
Cytoplast™ Non-Resorbable Barrier Membranes, Titanium-Reinforced

Model Numbers

Ti250ANL-1, Ti250ANL-2	Ti150ANL-1, Ti150ANL-2
Ti250ANL30-1, Ti250ANL30-2	
Ti250AP-1, Ti250AP-2	
Ti250AS-1, Ti250AS-2	Ti150AS-1, Ti150AS-2
Ti250ATC-1, Ti250ATC-2	Ti150ATC-1, Ti150ATC-2
Ti250BL-1, Ti250BL-2	Ti150BL-1, Ti150BL-2
Ti250BLL-1, Ti250BLL-2	Ti150BLL-1, Ti150BLL-2
Ti250K2-1, Ti250K2-2	Ti150K2-1, Ti150K2-2
Ti250PD-1, Ti250PD-2	Ti150PD-1, Ti150PD-2
Ti250PL-1, Ti250PL-2	Ti150PL-1, Ti150PL-2
Ti250PLT-1, Ti250PLT-2	Ti150PLT-1, Ti150PLT-2
Ti250PP-1, Ti250PP-2	
Ti250PS-1, Ti250PS-2	Ti150PS-1, Ti150PS-2
Ti250PST-1, Ti250PST-2	Ti150PST-1, Ti150PST-2
Ti250PTC-1, Ti250PTC-2	Ti150PTC-1, Ti150PTC-2
Ti250XL-1, Ti250XL-2	Ti150XL-1, Ti150XL-2
Ti250XLK-1, Ti250XLK-2	Ti150XLK-1, Ti150XLK-2

CLASSIFICATION: Class IIB, Rule 8 According to Annex IX of the MDD

CONFORMITY ASSESSMENT ROUTE: Annex II (Full Quality Assurance System), excluding Section 4

WE HEREWITH DECLARE THAT THE ABOVE-MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:

EN ISO 13485	EN ISO 14971	EN ISO 62366-1	EN ISO 14155	EN ISO 15882	EN ISO 14161
EN ISO 22803	EN ISO 10993-1	EN ISO 10993-5	EN ISO 10993-6	EN ISO 10993-7	EN ISO 10993-10
EN ISO 11135	EN ISO 11138-2	EN ISO 11140-1	EN ISO 11607-1	EN ISO 11607-2	EN ISO 11737-1
EN ISO 11737-2	EN ISO 14644-1	EN ISO 14644-2	EN ISO 14698-1	EN 1041	EN 980
EN 556-1	EN ISO 15223-1	AAMI ST41	AAMI TIR 28	AAMI ST67	USP 71
ASTM D4332	ASTM F88	ASTM D4895	ASTM F1980	ASTM F2096	ASTM F1929
ASTM D4169	CEN 1422	ASTM D638	ASTM B265	ASTM F67	EN ISO 10993-9

NOTIFIED BODY: BSI Group The Netherlands B.V./CE 2797

(EC) CERTIFICATE(S): CE 670712

DATE OF DOC ISSUE: 02 SEPTEMBER 2022

SIGNATURE: Jessica Cedillo

Ms. Jessica Cedillo – Regulatory Affairs Associate OBI DOC-002A REV 2022-09