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
2514 AP, The Hague
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PRODUCT:

Product Name
Cytoplast™ Non-Resorbable Barrier Membranes

Model Numbers
GBR2530
GBR1224
TXT2530, TXT2530-1
TXT1230, TXT1230-1
TXT1224, TXT1224-1
TXT1220, TXT1220-1

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	EN ISO 10993-9		

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

(EC) CERTIFICATE(S): CE 670712

DATE OF DOC ISSUE: 11 APRIL 2022

SIGNATURE: Jessica Cedillo

Ms. Jessica Cedillo – Regulatory Affairs Associate

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