DECLARATION OF CONFORMITY

MANUFACTURER:

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

Representative
Mrs. Jessica Cedillo
Regulatory Affairs Associate

EUROPEAN REPRESENTATIVE:

Company Name
Emergo Europe

Address
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

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PRODUCT:

Product Name
RPM™ Reinforced PTFE Mesh

Model Numbers

RPM200ATCE	RPM200PDE	RPM200PSE	RPM200XLKE
RPM200ATCME	RPM200PDMLE	RPM200PSTE	RPM200XLKME
RPM200BLE	RPM200PDMRE	RPM200PTCE	
RPM200BLLE	RPM200PLE	RPM200PTCME	
RPM200K2E	RPM200PLTE	RPM200XLE	

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: 25 APRIL 2022

SIGNATURE:

Elizabeth Bastian –Director of Regulatory Affairs

OBI DOC-003A REV 2022-04