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
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PRODUCT:

Product Name
Pro-Fix™ Precision Fixation System

Model Numbers

PFMK20	PFTK12	PFBK12	PFDH	PFDB	PFDB56
PFDBCA	PFT	PFMF	PFMF-5	PFMF5	PFMF5-5
PFT3	PFT3-5	PFT4	PFT4-5	PFT5	PFT5-5
PFT8	PFT8-5	PFT10	PFT10-5	PFB8	PFB8-5
PFB10	PFB10-5	PFB12	PFB12-5	PFB14	PFB14-5

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

CONFORMITY ASSESSMENT ROUTE: Annex II (excluding Section 4)

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

STANDARDS APPLIED:

ASTM F136	ANSI ST79	AAMI TIR 12	AAMI TIR 39	AAMI TIR 30	ASTM F543
ASTM F2052	ASTM F2213	ASTM F2182	ASTM F2119	EN 1041	ISO 5832-3
EN ISO 10993-1	EN ISO 13485	EN ISO 14155	EN ISO 14644-1	EN ISO 14644-2	EN ISO 14698-1
EN ISO 14698-2	EN ISO 14971	EN ISO 15223-1	EN ISO 17664	EN 62366-1	EN ISO 17665-1
ASTM F86	EN ISO 10993-9				

NOTIFIED BODY: BSI Group The Netherlands/CE 2797

(EC) CERTIFICATE(S): CE 670712

DATE OF DOC ISSUE: 22 DECEMBER 2021

SIGNATURE: Jessica Cedillo

Mrs. Jessica Cedillo – Regulatory Affairs Associate

OBI DOC-005A Rev 2021-12