DECLARATION OF CONFORMITY

MANUFACTURER:

Company
Osteogenics Biomedical, Inc.
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Representative
Mrs. Jessica Cedillo
Regulatory Affairs Associate

EUROPEAN REPRESENTATIVE:

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PRODUCT:

Product Name
Cytoplast™ PTFE Suture

Model Numbers

CS0418	CS0418SS	CS0428	CS0428SS				
CS0518	CS0518SS	CS0518BK	CS0518BKSS	CS051819	CS051819SS	CS051819BK	CS051819BKSS
CS0523	CS0523SS	CS0523BK	CS0523BKSS	CS052619	CS052619SS	CS052619BK	CS052619BKSS
CS0528	CS0528SS	CS0528BK	CS0528BKSS	CS052819	CS052819SS	CS052819BK	CS052819BKSS
CS0618PERIO	CS0618PERIOSS	CS0618PREM	CS0618PREMSS	CS0618RC	CS0618RCSS	CS0628PERIO	CS0628PERIOSS
CS0628PREM	CS0628PREMSS	CS0628RC	CS0628RCSS				
CS071813	CS071813SS	CS071816	CS071816SS	CS072813	CS072813SS	CS072816	CS072816SS

CLASSIFICATION: Class IIA, Rule 7 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 THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:

ASTM D4895	ASTM D4169	ASTM F88	ASTM F1980	ASTM F2096	ASTM D4332	ASTM F754
EN 1041	EN ISO 15223-1	EN ISO 10993-1	EN ISO 10993-5	EN ISO 10993-7	EN ISO 11135	EN ISO 11138-2
EN ISO 11607-1	EN ISO 11607-2	EN ISO 11737-1	EN ISO 13485	EN ISO 14155	EN ISO 14644-1	EN ISO 14644-2
EN ISO 14698-1	EN ISO 14971	EN 62366	EP 0324	EN 556-1	USP 42-NF37	EN ISO 10993-9
JIS G4308	ISO 16143-1	ISO 16143-2				

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

(EC) CERTIFICATE(S): CE 670712

DATE OF ISSUE: 26 JANUARY 2022

SIGNATURE:

Mrs. Jessica Cedillo – Regulatory Affairs Associate

OBI DOC-004A REV 2022-01