By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 670712**

Issued To: **Osteogenics Biomedical, Inc.**
4620 71st Street
Building 78-79
Lubbock
Texas
79424
USA

In respect of:

Design and manufacture of sterile PTFE non-resorbable barrier membranes and meshes, sterile PTFE sutures, screw fixation system intended for end-user sterilization and sterile porcine derived collagen membrane for the area of dentistry.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-02-13** Date: **2020-05-19** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 670712

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Number	Device Name	Intended purpose per IFU
Class III		
---	Porcine derived collagen membrane	See CE 670713
Class IIb		
62481	Sterile PTFE Non-Resorbable Barrier Membranes	A temporarily implantable material (non-resorbable) indicated as a space-making barrier in the treatment of periodontal defects
62481	Sterile PTFE Non-Resorbable Barrier Membranes, Titanium-Reinforced	
63439	Titanium-Reinforced PTFE Mesh	A temporarily implantable material (non-resorbable) indicated for stabilization and support of alveolar bony defect sites.
61837	Screw Fixation System	Used to stabilize, fixate, and/or support bone grafts, bone filling materials, and/or barrier membranes used for regeneration of bone in the oral cavity.
Class IIa		
MD 0302	PTFE Suture	---

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