EC Certificate Full Quality Assurance System: Certificate US07/919

The management system of

Osteogenics Biomedical, Inc.

4620 71st Street, Building 78-79,
Lubbock, TX, 79424, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Sterile PTFE non-resorbable barrier membranes, Sterile PTFE non-resorbable barrier membranes with titanium reinforcement, sterile PTFE non-resorbable sutures, sterile perforated PTFE barrier membranes Pro-Fix Precision dental fixation system for the area of dentistry. Sterile Vitala® Porcine Derived Collagen Membrane. Sterile SYMBIOS® Collagen Membrane FR.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 17 October 2016 until 12 May 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 16 April 2019
Issue 7. Certified since 12 May 2007

Certification is based on reports numbered WW/MW 600343

Authorised by

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