bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 550398**

Issued To: **DSM Biomedical, Inc.**
d.b.a. DSM Biomedical
735 Pennsylvania Drive
Exton
Pennsylvania
19341
USA

In respect of:

The design, development and manufacture of sterile bioresorbable implants fabricated alone or from combinations of synthetic resorbable polymers, calcium phosphate and collagen. The design, development and manufacture of sterile and non-sterile kits and components for the separation and delivery of autologous blood components for muscle, connective tissue, wound, bone, dental and osteoarthritic applications and for separation and delivery of autologous bone marrow aspirate cell concentrate for connective tissue, bone, osteoarthritic and degenerative disc disease applications.

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: **2009-12-01** Date: **2020-07-21** 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.

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A member of BSI Group of Companies.