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By Royal Charter

EC Design-Examination Certificate

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

No. **CE 686790**

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

In respect of:

Meso Dental Membrane

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

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

Albert Roossien, Regulatory Lead

First Issued: **2018-01-25** Date: **2019-02-11** Expiry Date: **2023-01-01**

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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 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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EC Design-Examination Certificate

Supplementary Information to CE 686790

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[redacted]

Catalogue #	DSM Part #	Description
ZM1520	30073-01	15 x 20mm ZMatrix Porcine Peritoneum Collagen Membrane
ZM2030	30073-02	20 x 30mm ZMatrix Porcine Peritoneum Collagen Membrane
ZM3040	30073-03	30 x 40mm ZMatrix Porcine Peritoneum Collagen Membrane

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Certificate History

Date	Reference Number	Action
25 January 2018	8777121	First issue. Product codes for Meso Dental Membrane transferred from certificate CE 583404.
18 September 2018	8955847	Addition of product codes ZM1520, ZM2030 and ZM3040.
Current	7781095	Traceable to NB 0086.

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