DECLARATION OF CONFORMITY
Meso Dental Membrane (Class III)

We hereby declare that the distributed CE marked products, specified in the annexed product list, conform to the design covered by the EC Design Examination Certificate, reference number: **CE 686790**, re-issued on **11 February 2019**, and delivered by BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands, Notified Body Identification Number 2797, in accordance with Annex II of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices and modified by Directive 2007/47/EC. This declaration is based on the application of the Quality System approved for design, manufacture and final inspection of the products concerned, in accordance with Annex II of the EC-Directive.

The conformity of the full quality assurance system set out in Annex II, section 3, is described in the CE Marking of Conformity Certificate, reference number: **CE 550398**, first issued on 1 December 2009 and delivered by BSI.

In addition, we ensure and declare that the distributed CE marked products, as mentioned and falling within Class III, according to Annex IX, Rule 8 and 17 of the European Union requirements of 93/42/EEC, meet the provisions of the EC Directive which apply to them.

This Declaration of Conformity covers Meso Dental Membrane as specified in the annexed product list belonging to this declaration and is valid for the products concerned bearing the CE marking and manufactured at the following site:

Manufacturer: DSM Biomedical
735 Pennsylvania Drive
Exton, Pennsylvania 19341, USA

This Declaration of Conformity is issued under the sole responsibility of the manufacturer and all supporting documentation is retained at the premises of the manufacturer.

Authorized Representative:
DSM Biomedical B.V.
Urmonderbaan 22, 6167 RD Geleen
The Netherlands

Place & Date of Issue:
Exton, Pennsylvania, USA
16 NOV 2020

DocuSigned by:
Diana Osgood
Signer Name: Diana Osgood
Signing Reason: I approve this document
Signing Time: 11/16/2020 | 12:25 PM PST
D3750AD44EBD4FB89E263AD342E3F649

Diana Osgood, Regulatory Affairs Specialist

DocuSigned by:
John George
Signer Name: John George
Signing Reason: I approve this document
Signing Time: 11/17/2020 | 08:29 AM EST
36AD23575DFD4F7FA8E6C7ABB03DB686

John George,
Sr. Manager Post-Market Surveillance and Quality Systems

Annex: Product List
Meso Dental Membrane (Class III)

This product list belongs to the Declaration of Conformity identified by Meso Dental Membrane (Class III) and specifies the CE marked products that DSM Biomedical intends to distribute in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 and the requirements of 2007/47/EC. The manufacturer approves the placing of the CE Mark on all production of the products defined in this declaration from **16 NOV 2020** until such time as significant changes are made to the product design, starting materials or major subcontractors.

Table 1 identifies the products by part number, product name and size.

Table 1

ZMatrix™ Porcine Peritoneum Collagen Dental Membrane		
Catalog Number	**DSM PN**	**Product Name & Size**
ZM1520	30073-01	ZMatrix Porcine Peritoneum Collagen Dental Membrane, 15 X 20mm
ZM2030	30073-02	ZMatrix Porcine Peritoneum Collagen Dental Membrane, 20 X 30mm
ZM3040	30073-03	ZMatrix Porcine Peritoneum Collagen Dental Membrane, 30 X 40mm