BSI Group
Kitemark Court, Davy Avenue
Knowlhill, Milton Keynes, MK5 8PP

Manufacturer's Self Declaration – DSM Biomedical, Inc.

For confirmation of the fulfillment of the conditions specified in (EU) 2017/745 MDR Article 120.3 as amended by (EU) 2023/607, DSM Biomedical declares that the devices listed in **Annex I** comply with:

a) The devices continue to comply with Directive 93/42/EEC
b) The certificates were not withdrawn prior to the certificate expiry
c) Continue to undertake all activities that support the signed Declaration of conformity to Directive 93/42/EEC
d) No significant changes in design or intended purpose as described in MDR art. 120 (3) and MDCG 2020-3
e) The devices do not present an unacceptable risk to the health or safety of patients, users, or other persons, or to other aspects of the protection of public health
f) MDR compliant QMS by 26 May 2024 (BSI audit ref 3428484, audit performed 22-Feb 2023 – 23-Feb-2023)
g) MDR application and submission of the devices was made prior to 26 May 2024, see applicable dates in **Annex I**.

As DSM Biomedical, Inc. meets the requirements of the conditions specified above, this self declaration is the official notice to have these devices be placed on the EU market, though the transitional dates as specified in (EU) 2023/607.

Issued By:

DocuSigned by:
John George
Signer Name: John George
Signing Reason: I approve this document
Signing Time: 4/12/2023 | 16:17 PM EDT
John George 86AB2B0F6D4F7FA8E6C7ABB03DB686

Director Regulatory Affairs and Quality Assurance

Issued On:

12APR2023

Annex I: Devices Subject to Manufacturer Self Declaration

ZMatrix Porcine Peritoneum Collagen Membrane:	
Commercial name/trade name:	ZMatrix Porcine Peritoneum Collagen Membrane 15 X 20mm (PN ZM1520) ZMatrix Porcine Peritoneum Collagen Membrane 20 X 30mm (PN ZM2030) ZMatrix Porcine Peritoneum Collagen Membrane 30 X 40mm (PN ZM3040)
Type of device:	Periodontal Membrane
GMDN/EMDN code:	Q010301
Unique identification by UDI-DI or MD nomenclature code classification according to MDD or AIMDD:	M263MD00001GL
Classification according to MDD:	III
Notified Body name:	BSI
Notified body identification number MDD/AIMDD certificate:	Notified Body Number: 2797
Identification number of MDD/AIMDD certificate under which it was marketed under the MDD/AIMD:	CE 686790
Expiry date of MDD/AIMDD certificate under which it was placed on the market:	2023-01-01
The date of Agreement to submit to MDR:	2021-03-03
The date of submission under MDR:	2021-06-24