Biomatlante
Biologics Solutions

BIOMATLANTE 5, Rue Edouard Belin ZA les Quatre Nations 44360 Vigneux de Bretagne	IMPRIMES **EC DECLARATION OF CONFORMITY**	**IM5.22-EN** Version 2 Page : 1/2

Manufacturer: Biomatlante
ZA Les Quatre Nations
5 Rue Edouard Belin
44360 Vigneux de Bretagne
France

Notify Body: TÜV SÜD Product Service GmbH
Ridlerstraβe 65
80339 Munich
Allemagne
Identification N°: 0123

Product Category: Injectable Bone Substitute

Product Articles Numbers: See Attachments

We, Biomatlante, declare under our sole responsibility that the above mentioned products are compliant to the dispositions of the following EC Directive and to the provisions transposing this Directive into the code of the French Public Health.

Directive: Directive 93/42/CEE
Classification: Class III

Assessment of Conformity: Annex II
CE Certificates: *Annex II.3 :* G1 16 05 32283 045
Annex II.4 : G7 032283 0059 Rev.00

Expiry Date of Declaration of Conformity: 26 November 2022

These devices are manufactured in the European Union.

On: 19 July 2019
Place: Vigneux de Bretagne

Name of the authorized person: Nancy TRICHEREAU
Function of the authorized person: Quality and Regulatory Affairs Manager

Signature :

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SIRET 402 687 495 00026 - APE 241 E
N° INTRACOM ER 53 402 687 495 00026

Product Category : Injectable Bone Substitute

Trade name	Articles Numbers	Designations	Date of the 1st EC Market was affixed
4Matrix+	**4M1102PU025DE**	Injectable Bone Substitute 0,5mL (x1)	19/07/2019
4Matrix+	**4M1103PU350DE**	Injectable Bone Substitute 0,5mL (x2)	19/07/2019