

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

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

Product Category: Calcium Phosphate Bone Substitutes

Product References: See Appendix

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 17 11 32283 051
Annex II.4 : G7 17 12 32283 053

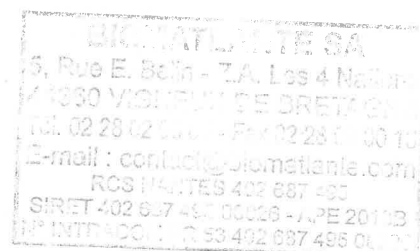
Expiry Date of Declaration of Conformity: 26 novembre 2022

These devices are manufactured in the European Union.

On: 06 December 2017
Place: Vigneux de Bretagne

Name of the authorized person: Mrs Chantal GOBIN
Function of the authorized person: CEO

Signature :



Product Category : Bone Substitute
EC Certificate Annex II.4 : G7 17 12 32283 053

Trade name	Model/article numbers	Designation	Date for 1st EC market was affixed
4BONE BCH	BS-4BS01	Granules 0.5-1mm (0.5cc)	26/07/2013
4BONE BCH	BS-4BS1S	Granules 0.5-1mm (1cc)	26/07/2013
4BONE BCH	BS-4BS25	Granules 1-2mm (2.5cc)	26/07/2013
4BONE BCH	BS-4BS60	Granules 1-2mm (6cc)	26/07/2013
4BONE	BS-4BS10	Granules 1-2mm (1cc)	01/02/2006
4BONE	BS-4BS20	Granules 1-2mm (2cc)	01/02/2006