



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 11 32283 051

Manufacturer: **Biomatlante SA**
ZA les Quatre Nations
5, Rue Edouard Belin
44360 Vigneux de Bretagne
FRANCE



Product Category(ies): **Calcium phosphate substitutes
(non-active implants)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713122306

Valid from: 2017-12-06
Valid until: 2022-11-26



Date, 2017-12-06

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Facility(ies):

Biomatlante SA ZA les Quatre Nations
5, Rue Edouard Belin, 44360 Vigneux de Bretagne, FRANCE