ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 16 05 32283 045

Manufacturer:

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

Product Category(ies):

Calcium phosphate bone substitutes; (non-active implants)
Resorbable fixation systems (Polylactic and composite screws; composite sheaths);
Collagen implants from porcin origin (Membranes)

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.: 713077573_2

Valid from: 2018-01-15
Valid until: 2022-11-26

Date, 2018-01-15

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

Biomatlante SA Pôle Bio-Ouest
Rue du Moulin de la Rousselière, 44800 Saint Herblain, FRANCE

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