



America

CERTIFICATE

No. QS6 032283 0058 Rev. 03

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

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of Calcium Phosphate, Bone Substitutes and Activity of Cleaning and Packaging of Medical Devices Sterile or Non-Sterile; Collagen Based Medical Devices, Polymer and Composites Implants with Associated Instruments and Calcium Phosphate Injectable Implants**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA. See attachment page for listing of specific regulatory requirements**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001188**

Effective Date: **2022-02-24**

Expiry Date: **2025-02-04**

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Date of Issue: 2022-02-25

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services

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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 16/2013
 - RDC ANVISA n. 23/2012
 - RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations – Part 1- SOR 98/282

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820

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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Facility Scopes:

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

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