



America

CERTIFICATE

No. QS6 043180 0043 Rev. 04

Certificate Holder: **B.T.I. Biotechnology Institute S.L.**
Parque Tecnológico de Álava Leonardo Da Vinci 14
01510 Miñano (Álava)
SPAIN

Certification Mark:



Scope of Certificate: **See Page 2 for Overall Scope Statement.**

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

Regulatory Authority(ies): **Health Canada, Japan MHLW / PMDA, USA FDA. See attached 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. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_043180_0043_Rev_04

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001195**
Report No.: **713334017**
Effective Date: **2024-10-07**
Expiry Date: **2027-10-06**

Page 1 of 3

Date of Issue: 2024-08-19

(Renee Walker)
Director, US Certification Body, MHS



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Regulatory Requirements: Audit/Certification Criteria

Canada

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

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
 - Japan PMD Act (as applicable)

United States

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

Overall Scope Statement:

Design and Development, Production, Distribution of Heating Blocks and Heating Ovens, Centrifuge, Collection and Fractionation Tubes, Activator (Accessory), Plasma Transfer Device, Single Use Kits to be used in the Technique for Obtaining Plasma Rich in Growth Factors (PRGF); Design and Development, Production, Distribution of Dental Implant Systems (included: Expander Implant Systems, Orthodontic Implant Systems and Osteosynthesis Screws System), Dental Surgical and Complementary Instrumental, Dental Drills and related Products; Medical Image Processing Software Systems and related Products, Sleep Apnea Diagnostic Devices and Auxiliary Materials; Servicing of Heating Blocks and Heating Ovens; Centrifuge; Ultrasonic Equipment for Bone Surgery, Torque Wrenches, Sleep Apnea Diagnostic Devices

Facility(ies):

B.T.I. Biotechnology Institute S.L.

Parque Tecnológico de Álava Leonardo Da Vinci 14, 01510 Miñano (Álava), SPAIN

B.T.I. Biotechnology Institute S.L.

Parque Tecnológico de Álava, Hermanos Elhuyar n. 4, 01510 Miñano (Álava), SPAIN

Page 2 of 3

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Page 3 of 3

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