



America

# CERTIFICATE

No. QS6 043180 0043 Rev. 02

**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, USA FDA, MHLW / PMDA. 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. Validity of this certificate can be obtained by visiting the website [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)

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

**REPs Facility ID:** **F001195**

**Effective Date:** **2021-11-19**

**Expiry Date:** **2024-11-18**

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**Date of Issue:** 2021-11-15

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



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**Regulatory Requirements:      Audit/Certification Criteria**

**Canada**

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

**Japan**

- MHLW Ministerial Ordinance 169, Article 4 to Article 68  
 - PMD Act

**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

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