



Certificate

No. Q5 043180 0042 Rev. 03

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

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of sterile dental implants and non-sterile accessories, sterile and non-sterile dental prosthetic components, invasive and non-invasive dental instruments and dental material, single use kits and sterile medical devices to be used in the technique for obtaining Plasma Rich in Growth Factors (PRGF), blood heaters and centrifuge, medical device software applications, sleep apnea diagnostic devices and related consumables.**
Servicing of blood heaters and centrifuge, medical device software applications, sleep apnea diagnostic devices and related consumables.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5_043180_0042_Rev.03

Report No.: 713334017

Valid from: 2024-10-25

Valid until: 2027-10-24

Date, 2024-10-02

Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

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

Design and development, distribution of single use kits and sterile medical devices to be used in the technique for obtaining Plasma Rich in Growth Factors (PRGF), blood heaters and centrifuge, medical device software applications, sleep apnea diagnostic devices and related consumables.

Design and development, production and distribution of sterile dental implants and non-sterile accessories, sterile and non-sterile dental prosthetic components, invasive and non-invasive dental instruments and dental material.

B.T.I. Biotechnology Institute S.L.
Parque Tecnológico de Álava, Hermanos Elhuyar n. 4, 01510
Miñano (Álava), SPAIN

Production of single use kits and sterile medical devices to be used in the technique for obtaining Plasma Rich in Growth Factors (PRGF), blood heaters and centrifuge, medical device software applications, sleep apnea diagnostic devices and related consumables.

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