



Certificate

No. Q5 043180 0042 Rev. 02

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, 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
(incl: expander implant systems, orthodontic implant Systems and osteosynthesis screws system)
- Dental surgical instruments and accessories, Dental drills and related prosthetic accessories
- Medical Image Processing Software Systems and accessories related
- Sleep Apnea Diagnostic Devices and accessories

Servicing of:

- Heating blocks and Heating ovens
- Centrifuge
- Ultrasonic equipment for bone surgery
- Torque wrenches
- Sleep Apnea Diagnostic Devices

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 and certification regulation of 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. 02

Report No.: 713214481
Valid from: 2021-10-27
Valid until: 2024-10-24

Date, 2021-10-27

Christoph Dicks
Head of Certification/Notified Body

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Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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

See Scope of Certificate.

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

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