Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 043180 0044 Rev. 00

Manufacturer:

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

Facility(ies):

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

Product Category(ies):

Medical Image Processing Software Systems (BTI Scan®) and accessories related.

PRGF® Plasmaterm Heating Devices, PRGF® Centrifuge, BTI Collection and Fractionation tubes, BTI Plasma Transfer Device and single use PRGF® Kits to be used in the technique for obtaining Plasma Rich in Growth Factors (PRGF®).

Sleep Apnea Diagnostic Devices and Accessories.

Dental implant systems (included: expander implant systems, orthodontic implant systems and osteosynthesis screws system), dental surgical instruments and accessories (excluding class I), dental drills and related prosthetic accessories.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713165545
Valid from: 2019-11-15
Valid until: 2024-05-26

Date, 2019-11-15

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany