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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

# EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

## No. G10 043180 0045 Rev. 02

**Manufacturer:**

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

SRN Manufacturer - ES-MF-000001701

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 043180 0045 Rev. 02

| | |
|---|---|
| **Report No.:** | 713410455 + 713333509 + 713333498 |
| **Preceding Certificate No.:** | G10 043180 0045 Rev. 01 |
| **Valid from:** | 2026-07-27 |
| **Valid until:** | 2028-04-17 |
| **Date of Initial Issuance:** | 2023-04-18 |

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2026-07-27


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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(Class IIa and Class IIb Devices)

## No. G10 043180 0045 Rev. 02

| | |
|---|---|
| **Classification:** | Class IIa |
| **Device Group:** | Z120190 - VARIOUS INSTRUMENTS FOR GENERAL AND MULTIDISCIPLINARY SURGERY |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | Class IIa |
| **Device Group:** | B030101 - APHERESIS PLASMA COLLECTION DEVICES |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | Class IIb |
| **Device Group:** | P010201 - DENTAL IMPLANTS AND ACCESSORIES |
| **Intended Purpose:** | BTI Dental Implant Systems consisting of dental implants, prosthetic components and dental accessory tools used in oral implantology to provide a support structure for the partial or total replacement of teeth in edentulous patients. |

| | |
|---|---|
| **Classification:** | Class IIa |
| **Device Group:** | Z12159099 - VARIOUS PNEUMOLOGY AND RESPIRATORY PHYSIOPATHOLOGY INSTRUMENTS - OTHER |
| **Intended Purpose:** | - |

| | |
|---|---|
| **Classification:** | Class IIa |
| **Device Group:** | Z12159092 - VARIOUS PNEUMOLOGY AND RESPIRATORY PHYSIOPATHOLOGY INSTRUMENTS - MEDICAL DEVICE SOFTWARE |
| **Intended Purpose:** | - |


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## No. G10 043180 0045 Rev. 02

| | |
|---|---|
| **Classification:** | Class IIa |
| **Device Group:** | Z12119092 - VARIOUS DENTAL STOMATOLOGY INSTRUMENTS - MEDICAL DEVICE SOFTWARE |
| **Intended Purpose:** | - |
| **The validity of this certificate depends on conditions and/or is limited to the following:** | ./. |

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2023-04-18 | 713260492 | Initial issuance |
| 01 | 2026-01-13 | 713301154 | Supplemented: Device(s)/group of device(s) added |
| 02 | 2026-07-27 | 713410455 + 713333509 + 713333498 | Supplemented: Device(s)/group of device(s) added<br>Supplemented: Change to the approved type(s)/device(s) |


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