



## 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. 00**

**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 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:G10 043180 0045 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G10 043180 0045 Rev. 00)

**Report No.:** 713260492

**Valid from:** 2023-04-18

**Valid until:** 2028-04-17

**Issue date:** 2023-04-18

Christoph Dicks  
Head of Certification/  
Notified Body



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### No. G10 043180 0045 Rev. 00

**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:** -

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