ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

Product Service

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 031072 0095 Rev. 02

Manufacturer:

Miltenyi Biotec B.V. & Co. KG
Friedrich-Ebert-Str. 68
51429 Bergisch Gladbach
GERMANY

SRN Manufacturer - DE-MF-000005273

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 031072 0095 Rev. 02

Report No.: 713280902 & 713194213

Preceding Certificate No.: G10 031072 0095 Rev. 01

Valid from: 2023-11-13
Valid until: 2025-10-19

Date of Initial Issuance: 2020-10-20

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-11-13

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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No. G10 031072 0095 Rev. 02

Classification:	Class IIa
Device Group:	B0103 - MEDULLARY BLOOD COLLECTION, PURIFICATION, CRYOPRESERVATION BAGS AND KITS
Intended Purpose:	-

Classification:	Class IIb
Device Group:	A0399 - TUBULAR DEVICES - OTHER
Intended Purpose:	Separation column for extracorporeal removal of cells or other blood components

Classification:	Class IIb
Device Group:	Z12170402 - THERAPEUTIC APHERESIS EQUIPMENT
Intended Purpose:	Instrument for extracorporal removal of cells and other blood components

Classification:	Class IIb
Device Group:	F01080102 - IMMUNOADSORPTION COLUMNS
Intended Purpose:	Separation column for extracorporal removal of cells or other blood components

Classification:	Class IIa
Device Group:	B0380 - APHERESIS DEVICES - ACCESSORIES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	D99 - DISINFECTANTS, ANTISEPTICS, STERILISING AGENTS AND DETERGENTS FOR MEDICAL DEVICES - OTHER
Intended Purpose:	-

Classification:	Class IIb
Device Group:	V9099 - VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES - OTHER
Intended Purpose:	Buffer or Reagent for extracorporal removal of cells or other blood components

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No. G10 031072 0095 Rev. 02

The validity of this certificate depends on conditions and/or is limited to the following: none

Revision History:

Rev.	Dated	Report	Description
00	2020-10-20	713180116	-
01	2022-10-10	713210124	-
02	2023-11-13	713280902 & 713194213	Supplemented: Device(s)/group of device(s) added

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