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 Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 031072 0114 Rev. 00

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 drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation 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 technical documentation assessment included an assessment of the clinical evaluation assessment. The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate. 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:G70 031072 0114 Rev. 00

Report No.: 713191486

Valid from: 2022-06-15
Valid until: 2027-06-14

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-06-15

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. G70 031072 0114 Rev. 00

Classification:	III
Device Group:	V9099 - VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES - OTHER
Basic UDI-DI:	4049934B000045S
Intended Purpose:	The CliniMACS Reagents and Biotin Conjugates are intended for in vitro magnetic labeling of human cells to enable the separation of specific human cells with a CliniMACS System for clinical applications.
Device(s):	CliniMACS Reagents and Biotin Conjugates covers in total 15 variants listed at the end of this Certificate
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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Trading name:	Article number:
CliniMACS CD34 Reagent	REF 171-01
CliniMACS CD56 Reagent	REF 271-01
CliniMACS CD19 Reagent	REF 179-01
CliniMACS Anti-Biotin Reagent	REF 173-01
CliniMACS CD3 Reagent	REF 273-01
CliniMACS CD14 Reagent	REF 272-01
CliniMACS CD8 Reagent	REF 275-01
CliniMACS Cytokine Capture System (IFN-gamma)	REF 279-01
CliniMACS CD4 Reagent	REF 276-01
CliniMACS CD25 Reagent	REF 274-01
CliniMACS CD1c (BDCA-1)-Biotin	REF 277-01
CliniMACS CD304 (BDCA-4) Reagent	REF 278-01
CliniMACS CD45RA Reagent	REF 701-46
CliniMACS CD45RA Reagent XS	REF 200-070-126
CliniMACS TCR alpha/beta-Biotin	REF 701-48

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