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

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 031072 0068 Rev. 06

Holder of Certificate: **Miltenyi Biotec B.V. & Co. KG**
Friedrich-Ebert-Str. 68
51429 Bergisch Gladbach
GERMANY

Certification Mark:

Scope of Certificate:

Design and Development, Production, Distribution and Servicing of Cell Separation Systems, Cell Cultivation Systems, Cell Storage Systems and Extracorporeal Blood Treatment Systems.
Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Hematology/Immunohematology.
Design and Development, Production, Distribution and Servicing of In Vitro Diagnostic Instruments for Hematology/Immunohematology.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 031072 0068 Rev. 06

Report No.: 713373761

Valid from: 2025-10-28
Valid until: 2028-01-30

Date, 2025-10-28

Christoph Dicks
Head of Certification/Notified Body

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

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

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Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

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

Design and Development, Production, Distribution and Servicing of Cell Separation Systems, Cell Cultivation Systems, Cell Storage Systems and Extracorporeal Blood Treatment Systems.
Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Hematology/Immunohematology.
Design and Development and Servicing of In Vitro Diagnostic Instruments for Hematology/Immunohematology.

Miltenyi Biotec B.V. & Co. KG
Robert-Koch-Strasse 1, 17166 Teterow, GERMANY

Design and Development, Production and Distribution of Cell Separation Systems, Cell Cultivation Systems, Cell Storage Systems, Cell Analysis Systems and Extracorporeal Blood Treatment Systems.

Miltenyi Biotec B.V. & Co. KG
Neurather Ring 1, 51063 Köln, GERMANY

Production and Distribution of Cell Separation Systems, Cell Cultivation Systems, Cell Storage Systems, Cell Analysis Systems and Extracorporeal Blood Treatment Systems.
Production and Distribution of In Vitro Diagnostic Instruments for Hematology/Immunohematology.

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