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

MDSAP
Medical Device Single Audit Program

America

CERTIFICATE

No. QS6 031072 0079 Rev. 06

Certificate Holder: **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, Extracorporeal Blood Treatment Systems and In-Vitro Diagnostic Cell Analysis Systems**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 031072 0079 Rev. 06
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001289**
Report No.: **713373761**
Effective Date: **2025-12-09**
Expiry Date: **2028-01-28**

Date of Issue: 2025-12-10

(Renee Walker)
Director, US Certification Body, MHS

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

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

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

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

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Facility Scopes:

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, Extracorporeal Blood Treatment Systems and In-Vitro Diagnostic Cell Analysis Systems

REPs Facility ID: F001289

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

REPs Facility ID: F002202

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

REPs Facility ID: F007128

Date of Issue: 2025-12-10

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