MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 031072 0079 Rev. 00

Certificate Holder: **Miltenyi Biotec GmbH**
Friedrich-Ebert-Str. 68
51429 Bergisch Gladbach
GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Cell Separation Systems, Cell Storage Systems, and In-Vitro Diagnostics for Cell Analysis**

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

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. 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. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **32-703-6034**

Effective Date: **2019-01-29**

Expiry Date: **2022-01-28**

Date of Issue: 2019-02-22

(Arie Henkin)
Manager, Certification Body MHS

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

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

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies):

Miltenyi Biotec GmbH
Friedrich-Ebert-Str. 68, 51429 Bergisch Gladbach, GERMANY

Miltenyi Biotec GmbH
Niederlassung Teterow, Robert-Koch-Strasse 1, 17166
Teterow, GERMANY

Date of Issue: 2019-02-22

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Facility Scopes:

Miltenyi Biotec GmbH
Friedrich-Ebert-Str. 68, 51429 Bergisch Gladbach, GERMANY

Design and Development, Production and Distribution of Cell Separation Systems, Cell Storage Systems, and In-Vitro Diagnostics for Cell Analysis
DUNS No: 32-703-6034

Miltenyi Biotec GmbH
Niederlassung Teterow, Robert-Koch-Strasse 1, 17166 Teterow, GERMANY

Design and Development, Production and Distribution of Cell Separation Systems, Cell Storage Systems, and In-Vitro Diagnostics for Cell Analysis
DUNS No: 33-298-4066

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