



America

CERTIFICATE

No. QS6 040330 0163 Rev. 03

Certificate Holder: DiaMed GmbH
Pra Rond 23
1785 Cressier FR
SWITZERLAND

Certification Mark:



Scope of Certificate: Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Medical Devices (Products, Reagents, Instruments and Software) for Immunohaematology, Haematology and Immunochemistry

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Brazil ANVISA, Health Canada, Japan 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. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_040330_0163_Rev.03

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

REPs Facility ID: F001662
Report No.: 713332262
Effective Date: 2024-10-03
Expiry Date: 2027-10-02

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Date of Issue: 2024-09-06

(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

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

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)

Facility(ies):

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