MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 040330 0163 Rev. 00

Certificate Holder:

DiaMed GmbH
Pra Rond 23
1785 Cressier FR
SWITZERLAND

Certification Mark:

Scope of Certificate:

Design and Development, Manufacturing and Distribution of In-Vitro Diagnostic Medical Devices for Immunhaematology, Haematology, Immunochemistry, Coagulation and Infectious Diseases

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

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, 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: **48-071-1659**

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Expiry Date: **2021-10-02**

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(Arie Henkin)

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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

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

Facility(ies):
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Pra Rond 23, 1785 Cressier FR, SWITZERLAND

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