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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 040330 0163 Rev. 01

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, 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 www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001662**

Effective Date: **2021-10-13**

Expiry Date: **2024-10-02**

Date of Issue: 2021-10-15

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services

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C E R T I F I C A T E

No. QS6 040330 0163 Rev. 01

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

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

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

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

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