





CERTIFICATE

No. QS6 099198 0003 Rev. 00

Certificate Holder:

DiaSpect Medical GmbH

Ebendorfer Chaussee 3

39179 Barleben GERMANY

Certification Mark:



Scope of Certificate:

Design and Development, Production, Distribution and Service of Photometric In-Vitro Diagnostic Systems for Analysis

of Blood Components

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

Australia TGA, Brazil ANVISA, Health Canada, 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. 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:

34-105-0309

Effective Date:

2018-11-07

Expiry Date:

2021-11-06

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Date of Issue: 2018-11-08

(Arie Henkin)

Manager, Certification Body MHS

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US-Letter / 07.17





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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

Facility(ies):

DiaSpect Medical GmbH

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