



America

CERTIFICATE

No. QS6 099198 0003 Rev. 05

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, Japan
MHLW / PMDA, 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. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_099198_0003_Rev_05

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

REPs Facility ID:

F002667

Report No.:

713317054

Effective Date:

2024-04-03

Expiry Date:

2027-04-02

Page 1 of 2

Date of Issue: 2024-04-09

(Renee Walker)
Director, US Certification Body, MHS

CERTIFICATE

No. QS6 099198 0003 Rev. 05

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.155 (2020)
- Japan PMD Act (as applicable)

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

DiaSpect Medical GmbH

Ebendorfer Chaussee 3, 39179 Barleben, GERMANY

Facility Scopes:

Design and Development, Production, Distribution and Service of Photometric In-Vitro Diagnostic Systems for Analysis of Blood Components
REPs Facility ID: F002667

Page 2 of 2

Date of Issue: 2024-04-09



(Renee Walker)
Director, US Certification Body, MHS