

**MDSAP**

Medical Device Single Audit Program



America

CERTIFICATE

No. QS6 128580 0001 Rev. 00

Certificate Holder:**MacroArray Diagnostics GmbH**

Lemböckgasse 59, Top 4

1230 Wien

AUSTRIA

Certification Mark:**Scope of Certificate:****Design and Development, Manufacture, Installation,
Service and Distribution of In-Vitro Diagnostic Reagents,
In-Vitro Diagnostic Instruments and In-Vitro Diagnostic
Analysis Software used in the Diagnosis of Allergy and
Food Intolerance****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. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6 128580 0001 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:QS6_128580_0001_Rev.00)

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

REPs Facility ID:**F008051****Report No.:****713348430****Effective Date:****2025-08-02****Expiry Date:****2028-08-01**

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(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

United States

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

Facility(ies):

MacroArray Diagnostics GmbH

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