

Certificate of Registration

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2025-08-02

Cycle start date

2025-08-02

Effective date

2026-07-17

Expiry date

2028-08-01

**MacroArray Diagnostics GmbH**

Lemböckgasse 59
Top 4
1230 Vienna AUSTRIA

Facility ID: F009118

UL LLC, UL Solutions medical and regulatory services issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016**EN ISO 13485:2016/A11:2021**

with additional regulatory requirements listed on the final page of this 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.

Certificate with Addendum(s) totals 3 pages.

Authorized by:

A handwritten signature in black ink, appearing to read 'P. Daysh'.

Paul Daysh
Operations manager – Medical Regulatory



Check certificate status: [here](#)

This quality system registration is included in UL's Product iQ directory and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown. By issuance of this certificate, the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferrable and remains the property of UL Solutions.

**UL LLC, UL Solutions medical regulatory services
is an MDSAP Recognized Auditing Organization**

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

Addendum 1

Site	Company Name	Location	Performing
1-1	MacroArray Diagnostics GmbH	Lemböckgasse 59 Top 4 1230 Vienna AUSTRIA Facility ID: F009118	Design, manufacturing, distribution, servicing

Additional Regulatory Requirements

MacroArray Diagnostics GmbH

Lemböckgasse 59
Top 4
1230 Vienna AUSTRIA

Facility ID: F009118

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
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

United States:

- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)