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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 112923 0001 Rev. 02

Certificate Holder: **UTAK Laboratories, Inc.**
25020 Avenue Tibbitts
Valencia CA 91355
USA

Certification Mark:

Scope of Certificate: **Design and Development, Manufacture and Distribution of In-Vitro Diagnostic Reagents used in the Detection of Drugs of Abuse, Therapeutic Drug Monitoring, and Trace Elements for Quality Control Purposes including Laboratory Use in Vitro-Diagnostic Devices**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, 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 112923 0001 Rev. 02
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F005870**
Report No.: **721007589**
Effective Date: **2025-06-18**
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Date of Issue: 2025-04-22

(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 4 – Production Quality Assurance Procedure

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): **UTAK Laboratories, Inc.**
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