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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 113784 0001 Rev. 00

Certificate Holder: **Asuragen, Inc.**
2150 Woodward St., Suite 100
Austin TX 78744
USA

Certification Mark:

Scope of Certificate: **Design, Development, Manufacture and Distribution of In-Vitro Diagnostic Reagents and In-Vitro Diagnostic Test Kits and their Calibrators and Controls, and Results Interpretation Software used in Clinical Applications, Diagnosis, Management and Detection of Cancer and Genetic Testing; Servicing of Results Interpretation Software**

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 113784 0001 Rev. 00
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F006453**
Report No.: **72177897**
Effective Date: **2023-11-03**
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(Renee Walker)
Director, US Certification Body, MHS

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C E R T I F I C A T E

No. QS6 113784 0001 Rev. 00

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): **Asuragen, Inc.**
2150 Woodward St., Suite 100, Austin TX 78744, USA

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