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

America

CERTIFICATE

No. QS6 033798 0011 Rev. 02

Certificate Holder: **Sakura Finetek U.S.A. Inc.**
1750 W. 214th Street
Torrance, CA 90501
USA

Certification Mark:

Scope of Certificate: **Design and Development, Production, Distribution, Installation, and Service of Reagents, Disposables, Components and Instrumentation used in the Preparation, Processing, Post Processing Manipulation and Recording of Diagnostic Specimens by Histology and Pathology Professionals**

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

Regulatory Authority(ies): **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 033798 0011 Rev. 02
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F002936**
Report No.: **721003530**
Effective Date: **2025-06-03**
Expiry Date: **2028-06-02**

Date of Issue: 2025-04-07

(Renee Walker)
Director, US Certification Body, MHS

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 033798 0011 Rev. 02

Regulatory Requirements: **Audit/Certification Criteria**

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.60 (2021)
- 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): **Sakura Finetek U.S.A. Inc.**
1750 W. 214th Street, Torrance, CA 90501, USA

Facility Scopes: Design and Development, Production, Distribution, Installation, and Service of Reagents, Disposables, Components and Instrumentation used in the Preparation, Processing, Post Processing Manipulation and Recording of Diagnostic Specimens by Histology and Pathology Professionals
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