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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 033798 0011 Rev. 00

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 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, USA FDA, MHLW / PMDA. 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. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

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

DUNS No: **17-913-5769**

Effective Date: **2019-06-03**

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Dawn Tibodeau

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Regulatory Requirements:

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies):

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