





Product Service

Certificate

No. Q5 033798 0010 Rev. 01

Holder of Certificate: 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 Equipment used in the Processing

of Diagnostic Samples by

Pathology Labs

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 033798 0010 Rev. 01

Report No.: 72173698

 Valid from:
 2022-05-19

 Valid until:
 2025-05-07

Date, 2022-05-19 Christoph Dicks

Head of Certification/Notified Body





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Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISÓ 13485:2016) DIN EN ISO 13485:2016

Facility(ies): Sakura Finetek U.S.A. Inc.

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Design and Development, Production, Distribution and Service of Reagents, Disposables, Components and Equipment used in the

Processing of Diagnostic Samples by Pathology Labs

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