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

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 033798 0010 Rev. 02

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 and distribution of in vitro diagnostic instruments and related consumables, of in vitro diagnostic reagents and general use consumables for Histology/Cytology used in the Processing of Diagnostic Samples by Pathology Professionals. Service and installation of in vitro diagnostic instruments.**

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, Certification, Validation and Verification Regulations 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. 02

Report No.: 721003530

Valid from: 2025-05-08
Valid until: 2028-05-07

Date, 2025-05-05

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

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Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

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

Design and development, production and distribution of in vitro diagnostic instruments and related consumables, of in vitro diagnostic reagents and general use consumables for Histology/Cytology used in the Processing of Diagnostic Samples by Pathology Professionals. Service and installation of in vitro diagnostic instruments.

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