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

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

TÜV SÜD Product Service

Certificate

No. Q5 108691 0001 Rev. 02

Holder of Certificate: **Sigma-Aldrich Corporation**
3050 Spruce Street
St. Louis MO 63103
USA

Certification Mark:

Scope of Certificate: **Design and development, manufacturing, and distribution of in-vitro diagnostic reagents and kits for use in histology, cytology and hematology.
The provision of manufacturing and distribution of reagents (ingredients and intermediates) for in-vitro diagnostic medical devices.
The provision of services for design and development of in-vitro diagnostic lateral flow assays.
The provision of services for manufacturing of synthetic oligonucleotides for in-vitro diagnostic medical devices.
The provision of services for manufacturing of in-vitro diagnostic reagents and kits for use in histology, cytology and hematology.**

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 108691 0001 Rev. 02

Report No.: 713316242

Valid from: 2024-06-07
Valid until: 2027-06-06

Date, 2024-05-29

Christoph Dicks
Head of Certification/Notified Body

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

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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):

Sigma-Aldrich Corporation
3050 Spruce Street, St. Louis MO 63103, USA

The provision of services for manufacturing of synthetic oligonucleotides for in-vitro diagnostic medical Devices. Customer service and technical services, final inspection and packaging.

Sigma-Aldrich Corporation
545 South Ewing Avenue, St. Louis MO 63103, USA

Design and development, manufacturing, and distribution of in-vitro diagnostic reagents and kits for use in histology, cytology and hematology.
The provision of services for design and development of in-vitro diagnostic lateral flow assays.
The provision of services for manufacturing of in-vitro diagnostic reagents and kits for use in histology, cytology and hematology.
Purchasing, packaging, final inspection, quality assurance and regulatory affairs.

Sigma-Aldrich Corporation
Second Street, H&H Facility, 3300 South Second Street, St. Louis MO 63118, USA

Manufacturing, packaging, and final inspection of in-vitro diagnostic reagents for histology, cytology and hematology.

Laclede
2909 Laclede Avenue, St. Louis MO 63103, USA

Design and development of in-vitro diagnostic reagents and kits for use in histology, cytology and hematology.

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Sigma-Aldrich LLC
3500 Dekalb Street, St. Louis MO 63118, USA

The provision of manufacturing of reagents (ingredients and intermediates) for in-vitro diagnostic medical devices.
Final inspection, packaging, and quality assurance.

Sigma-Aldrich LLC
2425 South Second Street, St. Louis MO 63104, USA

Distribution of in-vitro diagnostic reagents and kits for use inhistology, cytology and hematology.
The provision of distribution of reagents (ingredients and intermediates) for in-vitro diagnostic medical devices.

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