



Certificate

No. Q5 108691 0001 Rev. 00

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

Certification Mark:



Scope of Certificate: **Design and development, manufacturing, distribution and contract manufacturing of finished in-vitro diagnostic devices (reagents and kits) for use in histology, histochemistry, cytochemistry, cytology and hematology applications. Manufacturing and distribution of ingredients and reagents for use in an IVD product.**

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 108691 0001 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_108691_0001_Rev.00)

Report No.: 713190154

Valid from: 2021-06-07

Valid until: 2024-06-06

Date, 2021-06-07



Christoph Dicks

Head of Certification/Notified Body

Certificate

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Customer service and technical services

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

Manufacturing, purchasing, contract manufacturing, QC testing,
packaging, 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 QC testing

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

Design & Development

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

Manufacturing, QC testing, packaging, and quality assurance

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

Distribution

Parameters:

-/-