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

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 134730 0001 Rev. 00

Holder of Certificate: **LumiraDx UK Ltd**
Dumyat Business Park
Bond Street
Tullibody
Alloa, Clackmannanshire FK10 2PB
UNITED KINGDOM

Certification Mark:

Scope of Certificate: **Design and development, manufacture, distribution and servicing, and provision of design, development and manufacturing services of in-vitro diagnostic medical devices (reagents / reagent products / control materials / instruments) including general use consumables for sample collection and transport in the areas of clinical chemistry, immunochemistry, haematology / haemostasis and infectious immunology**

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 134730 0001 Rev. 00

Report No.: 75966192

Valid from: 2026-03-13
Valid until: 2029-03-12

Date, 2026-03-13

Christoph Dicks
Head of Certification/Notified Body

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

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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):

LumiraDx UK Ltd
Dumyat Business Park, Bond Street, Tullibody, Alloa, Clackmannanshire FK10 2PB, UNITED KINGDOM

Manufacture and servicing, and provision of manufacturing services of in-vitro diagnostic medical devices (reagents / reagent products / control materials / instruments) including general use consumables for sample collection and transport in the areas of clinical chemistry, immunochemistry, haematology / haemostasis and infectious immunology

LumiraDx UK Ltd
5 Dovecote Road, Eurocentral, Motherwell, North Lanarkshire ML1 4GP, UNITED KINGDOM

Manufacture, and provision of manufacturing services of in-vitro diagnostic medical devices (reagents / reagent products / control materials) including general use consumables for sample collection and transport in the areas of clinical chemistry, immunochemistry, haematology / haemostasis and infectious immunology

LumiraDx UK Ltd
39 Inchmuir Road, Whitehills Industrial Estate, Bathgate, West Lothian EH48 2EP, UNITED KINGDOM

Manufacture and distribution, and provision of manufacturing services of in-vitro diagnostic medical devices (reagents / reagent products / control materials) including general use consumables for sample collection and transport in the areas of clinical chemistry, immunochemistry, haematology / haemostasis and infectious immunology

LumiraDx UK Ltd
Manor Farm Business Park, Manor Loan, Stirling, Stirlingshire FK9 5QD, UNITED KINGDOM

Design and development, product support, and provision of design and development services of in-vitro diagnostic medical devices (reagents / reagent products / control materials) including general use consumables for sample collection and transport in the areas of clinical chemistry, immunochemistry, haematology / haemostasis and infectious immunology

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Product Service

Certificate

No. Q5 134730 0001 Rev. 00

LumiraDx UK Ltd
Maxim 9, Maxim Park, Eurocentral, Motherwell, North Lanarkshire ML1 4WQ, UNITED KINGDOM

Design and development, product support and post-market surveillance, and provision of design and development services of in-vitro diagnostic medical devices (reagents / reagent products / control materials / instruments) including general use consumables for sample collection and transport in the areas of clinical chemistry, immunochemistry, haematology / haemostasis and infectious immunology

Parameters: -

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