CERTIFICADO ◆ 인증서 ◆ CERTIFICATO ◆ 認証書 ◆ CERTIFICATE ◆ 认证证书 ◆ ZERTIFIKAT

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

Certificate

No. Q5 133411 0002 Rev. 00

Holder of Certificate: **SureScreen Diagnostics Limited**
Unit 17 Eagle Park
Alfreton Road
Derby, DE21 4BF
UNITED KINGDOM

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and Development, Manufacture and Distribution of lateral-flow based In-Vitro Diagnostic reagents and kits for Clinical Chemistry, Immunochemistry (Immunology), and Infectious Diseases.**
The provision of distribution service for In-Vitro Diagnostic reagents and kits for Clinical Chemistry, Immunochemistry (Immunology), Infectious Diseases and the provision of distribution service for 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 133411 0002 Rev. 00

Report No.: 75964880

Valid from: 2026-11-02
Valid until: 2029-11-01

Date, 2026-11-02

Christoph Dicks
Head of Certification/Notified Body

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

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Certificate

No. Q5 133411 0002 Rev. 00

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):

SureScreen Diagnostics Limited
Unit 17 Eagle Park, Alfreton Road, Derby, DE21 4BF, UNITED KINGDOM

Design and Development, Manufacture and Distribution of lateral-flow based In-Vitro Diagnostic reagents and kits for Clinical Chemistry, Immunochemistry (Immunology) and Infectious Diseases.

SureScreen Diagnostics Limited
Unit 9 Eagle Park, Alfreton Road, Derby, DE21 4BF, UNITED KINGDOM

The provision of distribution service for In-Vitro Diagnostic reagents and kits for Clinical Chemistry, Immunochemistry (Immunology), Infectious Diseases and the provision of distribution service for Diagnostic Instruments.

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