



# Certificate

No. Q5 113961 0001 Rev. 00

Holder of Certificate:

**Alba Bioscience Limited**

5 James Hamilton Way  
Milton Bridge, Penicuik, EH26 0BF  
UNITED KINGDOM

Certification Mark:



Scope of Certificate:

Design, Development, Manufacture and Distribution of In Vitro Diagnostic Reagents for Use in Manual and Automated Immunohaematology and Infectious Immunology Testing

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 113961 0001 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_113961_0001_Rev_00)

Report No.: 713230840

Valid from: 2023-04-21

Valid until: 2026-04-20

Date, 2023-04-21

Christoph Dicks  
Head of Certification/Notified Body

I, LAUREN JANET RAE, SOLICITOR AND NOTARY PUBLIC  
certify that this is a true copy of the  
original certificate.

29 June 2023  
Edinburgh

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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):** **Alba Bioscience Limited**  
5 James Hamilton Way, Milton Bridge, Penicuik, EH26 0BF,  
UNITED KINGDOM

Design, Development, Manufacture and Distribution of In Vitro  
Diagnostic Reagents for Use in Manual and Automated  
Immunohaematology and Infectious Immunology Testing.

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I, LAUREN JANET RAE, SOLICITOR AND NOTARY PUBLIC  
certify that this is a true copy of the original  
certificate.

*Lauren Rae*

29 June 2023  
Edinburgh.