



Product Service

# 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

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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**  
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UNITED KINGDOM

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