



# Certificate

No. Q5 123789 0005 Rev. 01

**Holder of Certificate:** **Lorne Laboratories Ltd**  
Unit 1 Cutbush Park Industrial Estate  
Danehill  
Lower Earley, Berkshire RG6 4UT  
UNITED KINGDOM

**Certification Mark:**



**Scope of Certificate:** **Design and development, production and distribution of in vitro diagnostic reagents for immunohaematology (Blood Grouping).**

**Production and distribution of in vitro diagnostic reagents for Infectious Immunology and Immunochemistry (Immunology).**

**The provision of distribution services for nonactive medical devices.**

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 123789 0005 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_123789_0005_Rev.01)

**Report No.:** 75966237

**Valid from:** 2026-05-13

**Valid until:** 2029-05-12

**Date,** 2026-05-13

Christoph Dicks  
Head of Certification/Notified Body



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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):** **Lorne Laboratories Ltd**  
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 Berkshire RG6 4UT, UNITED KINGDOM

See Scope of Certificate.