



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 123789 0005 Rev. 00

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 non-active 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. 00

Report No.: 75959970_AR

Valid from: 2025-05-07
Valid until: 2028-05-06

Date, 2025-05-07

Christoph Dicks
Head of Certification/Notified Body



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 123789 0005 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):

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate, Danehill, Lower Earley,
Berkshire RG6 4UT, UNITED KINGDOM

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 non-active medical
devices.

-