



Product Service

Certificate

No. Q5 064555 0010 Rev. 02

Holder of Certificate: **Leica Biosystems Melbourne Pty Ltd**
495 Blackburn Road
Mt Waverley
Victoria 3149
AUSTRALIA

Facility(ies): **Leica Biosystems Melbourne Pty Ltd**
495 Blackburn Road, Mt Waverley, Victoria 3149, AUSTRALIA

See scope of certificate

Certification Mark:



Scope of Certificate: **Design and Development, Production, Distribution, Installation and Service of In Vitro Diagnostic Instruments for Use in Clinical Immunohistochemistry, Pathology, Hematology, Cytology and detection of Infectious Disease.**
Production and Distribution of In Vitro Diagnostic Reagents for use in Immunochemistry and detection of Infectious Disease.

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

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_064555_0010_Rev_02

Report No.: JA200350002760, JA200350002760_CN

Valid from: 2024-12-01
Valid until: 2027-11-30

Date, 2024-11-15

Christoph Dicks
Head of Certification/Notified Body