



Certificate

No. Q5 064555 0010 Rev. 01

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 and Service of In Vitro Diagnostic Instruments for Use in Clinical Immunohistochemistry, Pathology, Hematology, Cytology and Immunodiagnostics. Production and Distribution of Medical Device In Vitro Diagnostic Reagents for use in Immunodiagnostics.**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
DIN EN ISO 13485:2016

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 064555 0010 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_064555_0010_Rev_01)

Report No.: **JA1759023**

Valid from: **2021-12-01**

Valid until: **2024-11-30**

Date, **2021-11-19**



Christoph Dicks
Head of Certification/Notified Body