MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 064555 0009 Rev. 00

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

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**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW/PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **75-318-4944**

Effective Date: **2018-11-14**

Expiry Date: **2021-11-13**

Date of Issue: 2018-12-10

(Arie Henkin)
Manager, Certification Body MHS
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