ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 064555 0009 Rev. 02

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 Medical Devices used in the Diagnosis of Cancer, Cardiac Markers, Disease Status, Endocrine Disorders, Genetic Testing, Protein Metabolism, Transmissible Agents and Immunological Typing**

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 www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001692**

Effective Date: **2022-10-27**

Expiry Date: **2024-11-13**

Date of Issue: 2022-11-01

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

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C E R T I F I C A T E

No. QS6 064555 0009 Rev. 02

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):
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Facility Scopes:
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