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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 064555 0009 Rev. 05

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, Installation 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, Japan MHLW / PMDA, USA FDA. 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. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 064555 0009 Rev. 05
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001692**
Report No.: **JA200350002760**
Effective Date: **2024-11-14**
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(Renee Walker)
Director, US Certification Body, MHS

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C E R T I F I C A T E

No. QS6 064555 0009 Rev. 05

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. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

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

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

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

Facility(ies): **Leica Biosystems Melbourne Pty Ltd**
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