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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 004933 0004 Rev. 02

Certificate Holder: **DIAsource ImmunoAssays S.A.**
2, rue du Bosquet
1348 Louvain-la-Neuve
BELGIUM

Certification Mark:

Scope of Certificate: **Design and Development, Manufacture, and Distribution of In-Vitro Diagnostic Test Kits for Clinical Chemistry, Immunochemistry, and Infectious Immunology**

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

Regulatory Authority(ies): **Australia TGA, Health Canada, USA FDA, Japan 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. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 004933 0004 Rev. 02
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F005716**
Report No.: **713335144**
Effective Date: **2024-10-20**
Expiry Date: **2027-10-19**

Date of Issue: 2024-08-23

(Renee Walker)
Director, US Certification Body, MHS

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C E R T I F I C A T E

No. QS6 004933 0004 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

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): **DIAsource ImmunoAssays S.A.**
2, rue du Bosquet, 1348 Louvain-la-Neuve, BELGIUM

Facility Scopes: Design and Development, Manufacture, and Distribution of In-Vitro Diagnostic Test Kits for Clinical Chemistry, Immunochemistry, and Infectious Immunology
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