



America

# CERTIFICATE

No. QS6 004933 0004 Rev. 01

**Certificate Holder:****DIAsource ImmunoAssays S.A.**2, rue du Bosquet  
1348 Louvain-la-Neuve  
BELGIUM**Certification Mark:****Scope of Certificate:****Design, Development, Manufacture and Management of Outsourced Manufacturing of In-Vitro Diagnostic Test Kits used in the Diagnosis of Endocrinology, Infectious Diseases, Immunology, Autoimmunity and Cancer Markers****Standard(s):****ISO 13485:2016****Regulatory Authority(ies):****Australia TGA, 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](http://www.tuvsud.com/ps-cert)

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

**REPs Facility ID:****F005716****Effective Date:****2022-11-07****Expiry Date:****2025-11-06**

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**Date of Issue:** 2022-10-31

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



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## 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 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):

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

## Facility Scopes:

Design, Development, Manufacture and Management of Outsourced Manufacturing of In-Vitro Diagnostic Test Kits used in the Diagnosis of Endocrinology, Infectious Diseases, Immunology, Autoimmunity and Cancer Markers  
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