# Certificate of Approval

This is to certify that the Management System of:

## DIAsource Immuno Assays S.A.

2 Rue du Bosquet, 1348 Louvain La Neuve, Belgium
MDSAP Facility Identifier: F003794

has been audited by Lloyd's Register Quality Assurance and found to conform to the following audit criteria:

ISO 13485:2016

**Australia:**

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

**Canada:**

Medical Devices Regulations – Part 1- SOR 98/282

**Japan:**

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

**United States:**

21 CFR 803
21 CFR 806
21 CFR 807 – Subparts A to D
21 CFR 820

Cliff Muckleroy - Area Operations Manager Americas
Issued by: Lloyd's Register Quality Assurance, Inc.

Certificate approval number: LRQ00000703
Effective date: 2019 November 7
Expiry date: 2022 November 6
Certificate issue number: 10237367

Original approval:
MDSAP/ISO 13485 – 2019 November 7

Product Approval number: MDSAP – 0079246

The scope of this approval is applicable to:

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.

Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.