Certificate

TÜV Rheinland®

Certificate No.:	MD 1804154-1
Manufacturer:	**BioArray Solutions Ltd.** 35 Technology Drive, Suite 100 Warren NJ 07059 USA
REPs Facility ID:	F003970
Certification criteria:	ISO 13485:2016 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 Devices Regulations – Part 1 – SOR 98/282 United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
Scope:	Design, Development and Manufacture of IVD Reagents (HEA, RHD, HPA, RHCE BeadChip Kit and MIA FORA NGS-HLA typing kit) and controls (HEA BeadCheck Kit). Design, Development, Manufacture, Installation and Servicing of Instrumentation including the AIS Series Instruments and Software (BASIS for BeadChip Products and MIA FORA NGS-HLA typing Software) for the Diagnosis or Management of Blood Grouping, HLA Typing, Compatibility Testing, Prenatal and Donor screening.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	1092511-230
Issue Date:	2022-05-27
Effective Date:	2022-05-30
Expiry Date:	2025-05-29

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000020315?locale=en or calling 1-888-743-4652.

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