

# Certificate

Certificate No.: MD 1804154-1-2

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. 665/2022, RDC ANVISA n. 551/2021,  
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 and Development, Manufacture and Distribution of in-vitro  
diagnostic reagents used for human genetic testing in the fields of  
transplant diagnostics and transfusion medicine.  
Design and Development, Manufacture, Distribution, Installation and  
Servicing of in-vitro-diagnostic instrumentation and software used for  
human genetic testing in the fields of transplant diagnostics and  
transfusion medicine.

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.: 1184961-690

Issue Date: 2025-05-20

Effective Date: 2025-05-30

Expiry Date: 2028-05-29



Certification officer: Irene Carraretto  
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com>  
or calling 1-888-743-4652.

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The scope of certification also covers the following sites:

No.	Location	Scope
/01	BioArray Solutions Ltd. 35 Technology Drive Suite 100 Warren NJ 07059 USA  REPs Facility ID: F003970	Design and Development, Manufacture, Distribution of in-vitro-diagnostic reagents used for human genetic testing in the field of transfusion medicine. Design and Development, Manufacture, Distribution, and Installation and Servicing of software, and instrumentation used for human genetic testing in the field of transfusion medicine.  Manufacture and Distribution of in-vitro-diagnostic reagents for human genetic testing in the field of transplant diagnostics. Manufacture, Distribution, and Installation and Servicing of software, and distribution and Installation and Servicing of instrumentation used for human genetic testing in the field of transplant diagnostics.
/02	SIRONA GENOMICS, INC. 1916 Old Middlefield Way Mountain View CA 94043 USA  REPs Facility ID: F007156	Design and Development of in-vitro-diagnostic reagents and software used for human genetic testing in the fields of transplant diagnostics.



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