

# Certificate

## Quality Management System

**EN ISO 13485:2016**

**EN ISO 13485:2016/AC:2018**

**EN ISO 13485:2016/A11:2021**

Registration No.: SX 1804154-1

Certificate Holder: BioArray Solutions Ltd.  
35 Technology Drive Suite 100  
Warren NJ 07059  
USA

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.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1184961-100

Effective date: 2025-05-30

Expiry date: 2028-05-29

Issue date: 2025-05-20

Replaces certificate SX 1804154-1 issued 2024-04-10

*Irene Carraretto*

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USA

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o BioArray Solutions Ltd. 35 Technology Drive Suite 100 Warren NJ 07059 USA	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	c/o SIRONA GENOMICS,INC. 1916 Old Middlefield Way Mountain View CA 94043 USA	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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