

# Certificate

The Certification Body of  
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization  
**BioArray Solutions Ltd.**  
**35 Technology Drive, Suite 100**  
**Warren NJ 07059**  
**USA**

has established and applies a quality management system for medical devices  
for the following scope:

**see attachment**

Proof has been furnished that the requirements specified in

**EN ISO 13485:2016**

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-05-29  
Certificate Registration No.: SX 60139759 0001  
An audit was performed. Report No.: 60239238 001  
This Certificate is valid until: 2022-05-29

Certification Body



Date 2019-05-29



  
Dipl.-Ing. Sven Hoffmann

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com <http://www.tuv.com/safety>

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** SX 60139759 0001  
**Report No.:** 60239238 001



**Organization:** BioArray Solutions Ltd.  
35 Technology Drive, Suite 100  
Warren NJ 07059  
USA

**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.

**Certification Body**



**Date:** 2019-05-29



**Dipl.-Ing. Sven Hoffmann**