

# Certificate

**Quality Management System  
EN ISO 13485:2016**

Registration No.: SX 1804154-1

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.

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.: 1092511-40  
Effective date: 2022-05-30  
Expiry date: 2025-05-29  
Issue date: 2022-05-27



*D. Wiedemuth*

Dipl.-Ing. (FH) D. Wiedemuth  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany