EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1804154-1

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

Products: Annex II List A Products:

MicroArray HEA BeadChip Kit for the Determination of C, c, E, e & Kell Blood Groups

Annex II List B Products:

MIA FORA NGS-HLA Typing Kit
MIA FORA FLEX HLA Typing Kit
MIA FORA NGS FLEX HT HLA Typing Kit
MIA FORA NGS MFLEX HLA Typing Kit
MIA FORA NGS MFLEX HT HLA Typing Kit

Replaces Certificate, Registration No.: HL 60139758 0001

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 1101151-20

Effective date: 2022-03-17

Expiry date: 2025-05-26

Issue date: 2022-03-17

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.