TÜVRheinland®

EC Certificate

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

Registration No.: HL 60139758 0001

Report No.: 60239238 001

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

Products: see attachment for products included

Expiry Date: 2022-05-29

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.

Effective Date: 2019-05-29

Date: 2019-05-29

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dipl.-Ing. Sven Hoffmann

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

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Doc. 1/1, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60139758 0001
Report No.: 60239238 002

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

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

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Notified Body

Date: 2020-02-13

Katja Mierisch