TÜVRheinland®

EC Design-Examination Certificate
Directive 98/79/EC Annex IV, Section 4
In Vitro Diagnostic Medical Devices

Registration No.: IL 60150261 0001

Report No.: 60360009 001

Manufacturer:

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

Product Identification:

see attachment

Replaces Certificate, Registration No.: IL 60139757 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex IV, section 4 of the directive 98/79/EC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2024-05-26

Effective Date: 2020-06-26

Date: 2020-06-26

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dr. H. Lüdemann

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: IL 60150261 0001
Report No.: 60360009 001

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

In vitro diagnostic test intended for molecular determination of the allelic variants that indicate human erythrocyte antigen phenotypes in the Rh (C,c, E,e, V, VS), Kell (K, k, Kpa, Kb, Jsa, Jsb), Duffy (Fya, Fyb, GATA, Fyx), Kidd (Jka, Jkb), MNS (M, N, S, s, U, Uvar), Lutheran (Lua, Lub), Dombrock (Doa, Dob, Hy, Joa), Landsteiner-Wiener (LWa, LWb), Diego (Dia, Dib), Colton (Coa, Cob), Scianna (Sc1, Sc2) blood group system in human genomic DNA as an alternative to serology. The test also detects a mutation that determines the status of Hemoglobin S.

- HEA BeadChip Kit

The conformity assessment of the Notified Body is limited to Rh (C,c, E,e) and Kell (K)

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Dr. H. Lüdemann

Date: 2020-06-26