



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

Registration No.: IL 60139757 0001

Report No.: 60239240 001

Manufacturer:

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

Product  
Identification:

see attachment

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: 2020-06-06

Notified Body

Effective Date: 2019-05-29

Date: 2019-05-29



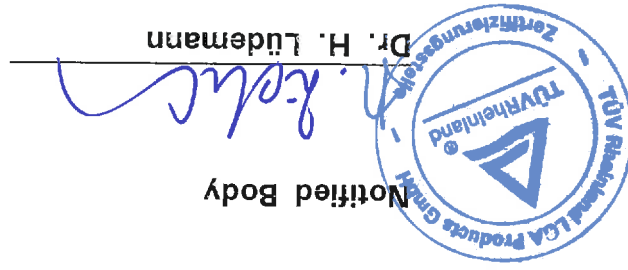
Dr. H. Lüdemann

*[Handwritten signature]*

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.

Date: 2019-05-29



- HEA Beadchip kit

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, Kpb, 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 (Scl, 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.

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Attachment to

TüV Rheinland  
 LGA Products GmbH  
 Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

