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 60110479 0001

Report No.: 21220926 003

Manufacturer:
Conexio Genomics Pty Ltd.
20 Collie St
Fremantle WA 6160
Australia

Products:
Tissue typing reagents

(see attachment of products included)

Replaces Certificate, Registration No.: HL 60099155 0001

Expiry Date: 2019-12-16

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: 2016-07-20

Date: 2016-07-20

Notified Body

Dipl.-Ing. C. Wiora

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. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HL 60110479 0001
Report No.: 21220926 003

Manufacturer:
Conexio Genomics Pty Ltd.
20 Collie St
Fremantle WA 6160
Australia

Products included:

- HLA SBT Typing Reagents HLA-A, -B, -DRB1 and associated primers used to assist in the resolution of heterozygous ambiguities arising from HLA sequencing based typing

Date: 2016-07-20

TÜV Rheinland LGA Products GmbH Zertifizierung

Notified Body

Dipl.-Ing. C. Wiora