



Certificate Number
AU Q00309

Australian Government

Department of Health
Therapeutic Goods Administration

Conformity Assessment Certificate

Full Quality Assurance Procedures

This is to certify that the quality management system described below complies with the relevant provisions of Schedule 3, Part 1 (excluding clause 1.6) of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Certification is based on an assessment of the Full Quality Management System, applied at each stage of medical device manufacture, from the design of a device until its final inspection before being supplied.

Manufacturer Name: Conexio Genomics Pty Ltd

Manufacturer Address: 2/49 Buckingham Drive
WANGARA WA 6065
Australia

Commencement Date: 19 May 2014

Certificate Expiry Date: 29 July 2018

This certificate has effect at all times from the commencement date, until the end of the period specified in the certificate (expiry date), or unless it has been suspended or revoked.

This certificate is issued under Section 41EE of the *Therapeutic Goods Act 1989* by:

Peter Kaylock

Signed electronically

Delegate of the Secretary

Office of Devices Authorisation

Therapeutic Goods Administration

PO Box 100, Woden ACT 2606 Australia



Australian Government

Department of Health
Therapeutic Goods Administration

Scope of Certificate

Manufacturer Facilities

| Name and Address | | Scope |
|------------------|---|---|
| 1. | Conexio Genomics Pty Ltd C/- Department of Clinical Immunology Level 2 North Block Royal Perth Hospital Wellington Street PERTH WA 6000 AUSTRALIA | Design and development, production, packaging, labelling, final release, warehousing and dispatch |

Device Categories

| Description | Limitations (if applicable) |
|--|--|
| 1. Multiple human leukocyte antigens (HLA) typing IVDs | 1. Nucleic acid based methods only 2. Device category excludes software |

Critical Suppliers

| Name and Address | | Scope |
|------------------|---|--|
| 1. | Olerup SSP AB Franzégatan 5 SE-112 51 STOCKHOLM Sweden | Kit assembly and packaging, warehousing and dispatch |



Certificate Number
AU Q00309

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate History

| Version | Details | Issue Date | File Reference |
|---|---|--------------|----------------|
| 1 | Initial certification | 29 July 2013 | 2012/014698 |
| 2 | Change in address of manufacturer— From: 8/31 Pakenham St FREMANTLE WA 6160 Australia To: 2/49 Buckingham Drive WANGARA WA 6065 Australia | 19 May 2014 | 2014/004653 |
| Certificate Location (Manufacturer Root File Number): | | | 2013/013482 |



Australian Government
Department of Health
Therapeutic Goods Administration

Conditions

The following conditions apply automatically under Section 41EJ of the *Therapeutic Goods Act 1989*:

Entry and inspection powers

- (1) A conformity assessment certificate is subject to the conditions that the manufacturer in respect of whom the certificate is issued will:
- (a) allow an authorised person:
 - (i) to enter, at any reasonable time, premises (including premises outside Australia) at which the person or any other person deals with medical devices of a kind covered by the certificate; and
 - (ii) while on those premises, to inspect those premises and medical devices of any kind on those premises and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of medical devices of any kind on those premises or any thing on those premises that relates to medical devices of any kind; and
 - (iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and
 - (b) if requested to do so by an authorised person:
 - (i) produce to the person such documents relating to devices of a kind covered by the certificate, or to the manufacturer's quality management system, as the person requires; and
 - (ii) allow the person to copy the documents.

Review

- (2) A conformity assessment certificate is subject to the condition that the manufacturer in respect of whom the certificate is issued will cooperate in any review by the Secretary of the certificate to determine whether the conformity assessment procedures relating to the following matters have been applied to the kinds of medical devices covered by the certificate:
- (a) the application of quality management systems for the manufacture of medical devices;
 - (b) the certification of compliance with the essential principles;
 - (c) any other requirement of the conformity assessment procedures specified in the regulations made for the purposes of subsection 41EC(2).

Notification of substantial changes

- (3) A conformity assessment certificate is subject to the condition that the person in respect of whom the certificate is issued will notify the Secretary, in writing, of any plan for substantial changes to:
- (a) quality management systems; or
 - (b) the product range covered by those systems; or
 - (c) the product design of kinds of medical devices;
- in respect of which the certificate is issued.

Fees

- (4) A conformity assessment certificate is subject to the condition that the applicant for the certificate will pay a fee, prescribed in the regulations, for a review under subsection (2), when the fee becomes due and payable.
- (5) The regulations may prescribe different levels of fees for different kinds of manufacturers and medical devices.

Conditions in regulations

- (5A) A conformity assessment certificate is subject to any conditions prescribed by the regulations for the purposes of this subsection.

Conditions do not limit other conditions

- (6) A condition imposed under this section is in addition to any conditions imposed under this Division.