Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Conexio Genomics Pty Ltd

for approval to supply

Multiple human leukocyte antigens (HLA) typing IVDs

ARTG Identifier	213561
ARTG Start date	22/08/2013
Product Category	Medical Device Included - IVD Class 3
GMDN	CT892
GMDN Term	Multiple human leukocyte antigens (HLA) typing IVDs
Intended Purpose	The SBT Resolver™ HLA typing kits are intended to be used in regulated tissue typing laboratories for donor selection and donor/recipient matching in transplantation. The devices amplify portions of the HLA genes which are sequenced by sequencing primers provided in the kits. The SBT Resolver™ HARPS are a family of approximately 80 supplementary sequencing primers whose specificities allow the resolution of ambiguities arising from DNA sequencing. Each HARP is sold separately and is intended to be used in conjunction with the SBT Resolver™ typing kits. The SBT Resolver™ B57 kit is intended to be used in regulated laboratories for HLA-B*57 screening.

Manufacturer Details	Address	Certificate number(s)
Conexio Genomics Pty Ltd	20 Collie Street Fremantle, WA, 6160 Australia	DV-2016-MC-15855-1

ARTG Standard Conditions

The above Medical Device Included - IVD Class 3 has been entered on the Register subject to the following conditions:

- The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.
- The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.
- For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.
- Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.
- The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.
- A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.
- It is a condition of inclusion in the ARTG that the sponsor of a medical device that is a Class 4 IVD provides three consecutive annual reports to the Head of the Office of Product Review, Therapeutic Goods Administration following inclusion of the device in the ARTG (as specified in 5.8 of the regulations). Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints and adverse events received by the

manufacturer relating to problems with the use of the device that have been received by them over the year.

- Goods which would require an application audit under Regulation 5.3 if subject to a separate application for entry in the Register cannot be included under this ARTG entry until a request to vary the entry has been submitted and approved by the TGA.

Products Covered by This Entry

1. Multiple human leukocyte antigens (HLA) typing IVDs

This entry: does not contain System(s)/Procedure Pack(s)

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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