



Australian Government
Department of Health
Therapeutic Goods Administration

Licence to Manufacture Therapeutic Goods – Part 1

Licence Number:

MI-23032005-LI-000486-1

Previously granted under Licence number: 101395

Granted to:

St Vincent's Hospital Sydney Ltd T/A Sydpath
ABN: 77 054 038 872

Manufacturing Site Address:

376 Victoria St
DARLINGHURST NSW 2010

The manufacturer above is hereby authorised under Section 38 of the *Therapeutic Goods Act 1989* to carry out the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Manufacturing Step
Testing Laboratory - Blood Tissue Cellular	Virology Screening and Syphilis Testing NAT Testing for HIV, HCV and HBV EIA testing for antibodies to malaria
Human Tissue	Microbiological Contamination Testing

This licence is subject to the requirements of the *Therapeutic Goods Act 1989*, and its Regulations. Section 40(4) of the *Therapeutic Goods Act 1989* and Regulation 19, 20, 21 and 22 of the Therapeutic Goods Regulations 1990 impose various statutory conditions on all licences to manufacture therapeutic goods.

No additional specific conditions have been imposed on this licence under Section 40(1) or 40(2) of the *Therapeutic Goods Act 1989* and consequently this licence does not have a Part 2.

Originally Granted: **20 October 1999**

Date Revised: **11 September 2017**

This Licence is the property of the Therapeutic Goods Administration and must be returned or destroyed upon demand. This Licence remains valid until otherwise suspended or revoked by the Therapeutic Goods Administration. The status of an Australian Licence may be viewed at <https://www.ebs.tga.gov.au/>