

Licence to Manufacture Therapeutic Goods

LICENCE NO: 1192

Manufacturer:

Global Medical Solutions Pty Limited t/a Radpharm Scientific ACN: 072 147 561

Manufacturing site for which the licence applies:

54-59 Oatley Crt BELCONNEN ACT 2617

The above manufacturer is hereby authorised to carry out the following kind(s) of manufacture:

Manufacture of sterile therapeutic goods for human use.

at the above manufacturing site, subject to the requirements of the *Therapeutic Goods Act 1989* and its Regulations and to the additional conditions imposed under Section 40 of the Act forming part of this licence.

Date Issued:

05/12/1994

Date Revised:

15/03/2007

Signed:

Delegate of the Secretary

This licence is the property of the Therapeutic Goods Administration and must be returned upon demand. This licence remains valid until otherwise suspended or revoked by the Therapeutic Goods Administration.



Schedule of Conditions Applicable to the Manufacture of Therapeutic Goods

The following conditions form part of Licence No. 1192 issued in respect of:

Global Medical Solutions Pty Limited t/a Radpharm Scientific 54-59 Oatley Crt BELCONNEN ACT 2617

Under the Therapeutic Goods Act, 1989

This licence authorised only the manufacture of therapeutic goods in the following product or product classes: terminally sterilised injectables in vials.

This licence does not authorise the manuacture of preparations containing hormones, steroids, antineoplastics, cephalosporins and penicillins.

The manufacturer is required to notify the TGA before the first batch of a preparation that is not a radiopharmaceutical cold kit, is manufactured on site.

Persons currently nominated as having control under Section 37 of the *Therapeutic Goods Act, 1989*:

Production:

Edith Gubicak

Quality Control:

Jacqui Whitwell

Originally Issued:

05/12/1994

Date Revised:

15/03/2007

Signed:

Delegate of the Secretary