EC Certificate Production Quality Assurance System: Certificate GB12/85101

The management system of

Sinapi Biomedical (Pty) Ltd.

ARC Infruitec North Campus, Lelie Road,
Stellenbosch, 7600, South Africa

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

Annex V Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions for sterile single use chest drain, without catheter.

Annex V Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions for sterile single use urine meter, without catheter.

Sterile and non sterile single use safety scalpel with blade

For placing on the market of Class IIb or Class III devices covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 01 March 2015 until 01 March 2020 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 October 2017
Issue 5. Certified since 01 March 2012

Certification is based on reports numbered GB/PI 227447

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 13 0311