EC Certificate Full Quality Assurance System: Certificate EG12/85101

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 II (excluding Section 4)

For the following products

Sterile single use chest drain, with catheter
Sterile single use urine meter, with catheter
Sterile and non sterile single use safety scalpel with blade

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 01 June 2016 until 01 March 2020 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 October 2017
Issue 2. Certified since 3 January 2012

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 02 0215