



EC Certificate Full Quality Assurance System: Certificate ES19/86764

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

The scope of registration appears on page 2 of this certificate

This certificate is valid from 09 April 2021 until 01 March 2023  
And remains valid subject to satisfactory surveillance audits.

Issue 4. Certified since 01 March 2012.

Certification is based on reports numbered ES/MAD-227447

Authorised by

Global Medical Devices Head of Notified Body

**SGS Belgium NV, Notified Body 1639**

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LFMD5007 - Certificate CE1639 Annex II-4 - EN rev. 02

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# Sinapi Biomedical (Pty) Ltd.

## Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

Issue 4

Detailed scope

**Sterile and non-sterile single use safety scalpel with blade**

**Sterile single use uterine balloon tamponade**

**Class I Measuring/Sterile: "Metrological and Sterile aspects only -**

**Restricted to the aspects of manufacture concerned with**

- the conformity of the devices with metrological requirements
- securing and maintaining sterile conditions"

**Sterile single use urine meter**

**Class I Sterile: "Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions"**

**Sterile single use chest drain**

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.