

EC Certificate Full Quality Assurance System: Certificate GB11/82170

The management system of

Clinisut (Pty) Ltd

25 Harrower Road, North End, Port Elizabeth, 6001, 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

Sutures:

Linen
Nylon
Polypropylene
Silk
Trofilene

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

This certificate is valid from 19 June 2012 until 07 January 2016 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 26 November 2013

Issue 2. Certified since 07 January 2011

Certification is based on reports numbered GB/PC 224870

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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Page 1 of 1

