Certificate GB11/83168

Clinisut (Pty) Ltd

21 McHardy Avenue, Holland Park,
Port Elizabeth 6001, South Africa

Device Identification:

CliniSorb braided sterile absorbable polyglycolic acid synthetic surgical sutures

Medical Purpose of Device:

For use in soft tissue approximation and/or ligation including use in ophthalmic procedures. Not for use in cardiovascular or neurological procedures.

has been assessed and certified as meeting the requirements of

EC Directive 93/42/EEC

on Medical Devices Annex II, section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to regular compliance visits.

This certificate is valid from 27 May 2011 until 27 May 2016
Issue 1

Certification is based on report number GB/PC DDE 224873 dated 12th May 2011

Addenda to that report have been issued on the following dates:

Addendum Date	Reason for Addendum
N/A	N/A

Notified Body Number 0120

Authorised by

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