EC Design Examination Certificate: Certificate GB11/83100

Clinisut (Pty) Ltd

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

Device Identification:

CliniMono Q monofilament sterile fast absorbing poly (glycolide-cocaprolactone) synthetic surgical sutures.

Intended Purpose of Device:

For use in superficial soft tissue approximation and/or ligation, but not for use in ophthalmic, cardiovascular or neurological procedures.

has been assessed and certified as meeting the requirements of

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 satisfactory surveillance audits.

This certificate is valid from 19 May 2011 until 19 May 2016
Issue 1

Certification is based on report number(s) GB/PC DDE 225461 dated 11 April 2011

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

Addendum Date	Reason for Addendum
N/A	N/A

Authorised by

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