



## APPROVAL OF CONFORMITY CERTIFICATE

**In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618**

This is to certify that the Quality Management System of:

**Clinisut (Pty) Ltd  
Port Elizabeth  
South Africa**

has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 0961718/B  
Original Approval: 17 February 2000  
Current Certificate: 17 October 2008  
Certificate Expiry: 31 January 2011  
LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



**APPROVAL OF CONFORMITY CERTIFICATE  
CERTIFICATE LRQ 0961718/B SCHEDULE**

**In accordance with the requirements of the Medical Devices  
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK  
Statutory Instrument 2002 No. 618**

**Clinisut (Pty) Ltd  
Port Elizabeth  
South Africa**

**Class II Products**

Sutures and Ligatures:  
CliniSilk (Silk)  
Clini-Ny (Nylon)  
Clini-Tro (PVDF)  
Clini-Lin (Linen)  
Clini-Ester (Polyester)  
CliniLene (Polypropylene)

**Class III Products**

PGA Absorbable Suture

**EC Design Examination Certificate**

0088/0961718/00098

Schedule Issue: 01

Date of Schedule Issue: 17 October 2008

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



## CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

**Clinisut (Pty) Ltd  
Port Elizabeth  
South Africa**

has been approved by Lloyd's Register Quality Assurance  
to the following Quality Management System Standards:

**ISO 9001:2000  
ISO 13485: 2003**

The Quality Management System is applicable to:

**Design, manufacture and sale of fine  
wound closure material.**

This certificate forms part of the approval identified by certificate number LRQ 0961718

Approval  
Certificate No: LRQ 0961718/A

Original Approval: 17 February 2000

Current Certificate: 22 October 2008

Certificate Expiry: 31 January 2011

Issued by: Lloyd's Register Quality Assurance Limited



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This document is subject to the provision on the reverse

71 Fenchurch Street, London EC3M 4BS United Kingdom. Registration number 1879370

This approval is carried out in accordance with the UKAS assessment and certification procedures and monitored by LRQA.

The use of the UKAS Accreditation Mark indicates Accreditation in respect of those activities covered by the Accreditation Certificate Number 001

Mark Issue 13