



EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE

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:

**FCL Health Solutions – Trading as Apex Surgical
Hawthorns House, Halfords Lane
Smethwick, B66 1DW
United Kingdom**

has been assessed against the requirements of Annex V 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 00000698/B

Original Approval: 7 June 2017

Current Certificate: 7 June 2017

Certificate Expiry: 6 June 2020

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited



**EC CERTIFICATE – PRODUCTION QUALITY ASSURANCE
CERTIFICATE LRQ 0000698/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**

**FCL Health Solutions – Trading as Apex Surgical
Hawthorns House, Halfords Lane
Smethwick, B66 1DW
United Kingdom**

Class IIa Products

Single Use Biopsy Forceps
Single Use Needle Holders
Single Use Ophthalmic Scissors
Single Use Scalpel Holders
Single Use Scissors
Single Use Surgical Forceps
Single Use Towel Forceps

Schedule Issue: 01

Date of Schedule Issue: 7 June 2017

LRQA Notified Body Number 0088



Issued by: Lloyd's Register Quality Assurance Limited