

EC Certificate Production Quality Assurance System: Certificate
GB08/74615

The management system of

Farla Medical Ltd

Unit 17, Grosvenor Way, London, E5 9ND, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate

For placing on the market of Class IIb or Class III devices covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

This certificate is valid from 01 July 2014 until 10 February 2019 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 03 February 2017

Issue 10. Certified since 28 April 2008

Certification is based on reports numbered GB/PC 216926

This is a multi-site certification.
Additional site details are listed on subsequent pages.

Authorised by

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SGS CE 13 0311 M2

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Farla Medical Ltd

Directive 93/42/EEC

on medical devices, Annex V

Issue 10

Detailed scope

Directive 93/42/EEC
on medical devices, Annex V

Sterile single use instruments for gynaecology, ophthalmology, podiatry, ENT and general surgery. Sterile Single Use Surgical sets, Sterile procedure packs and dressing packs. Sterile Surgical Gloves, Non sterile lubricating gel, Sterile irrigation solution for single use. Digital Thermometers

Annex V Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

Sterile single use instruments for gynaecology, ophthalmology, podiatry, ENT and general surgery. Sterile wound dressings, dressing packs and procedure packs. Sterile Examination Gloves. Sterile Gauze Swabs, Sterile Non-Woven Swabs, Sterile Lubricating jelly