EC Certificate Full Quality Assurance System: GB98/13394

The management system of

Meditech Systems Ltd

Shrublands Estate, Sherstock, Shaftesbury, Dorset, SP7 9PT, UK

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

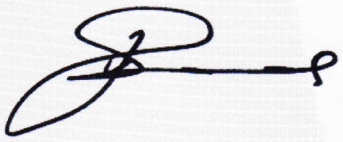
For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 31 March 2017 until 23 June 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 23 June 2019
Issue 31. Certified since 23 June 1998

Certification is based on reports numbered GB/PC 08743

Authorised by



SGS United Kingdom Ltd, Notified Body 0120

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Meditech Systems Ltd

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 31

Detailed scope

Sterile & non sterile single use and non sterile reusable breathing sets
Non sterile PEEP valves, APL valves
Sterile single use insufflation tube sets
Sterile single use & non sterile suction tips, yankauers and suction tubes
Non sterile oxygen delivery masks, nasal cannula and bite blocks.
Non sterile oxygen tubes
Non sterile corrugated tubes for oxygen, humdification and breathing system use
Non sterile air entrainment venturi jets
Non sterile nebulisers and nebuliser kits
Sterile single use & non sterile breathing system filters
(HEPA filter, HME filter, Electrostatic filter)
Non sterile anaesthesia reservoir bags
Non sterile breathing set connectors
Sterile single use & non sterile anaesthesia masks and CPR resuscitation masks.
Sterile surgically invasive HRT instrument sets and Colposcopy biopsy instrument sets.
Non sterile cricothyroidotomy insufflation device.
Sterile cricothyroidotomy insufflation procedure sets.
Sterile single use gynaecological biopsy punch
Non sterile manual resuscitator kits
Sterile & non sterile reusable electrosurgery monopolar and bipolar electrodes
Sterile & non sterile reusable electrosurgery forceps and scissors
Non sterile reusable electrosurgery fingerswitch pencils
Sterile single use electrosurgery fingerswitch pencil
Sterile single use dermal biopsy punch and sterile dermal curette

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

Sterile single use electrosurgical cables
Sterile single use gynaecological specula
Sterile single use ENT Specula
Sterile single use electrosurgical scratch/cautery pads
Sterile single use contraceptive coil insertion sets.
Sterile single use non invasive medical instruments and instrument sets
Sterile single use oropharyngeal and nasopharyngeal airways
Sterile single use laryngoscope blades for intubation

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market