

SGS

Certificate GB98/13393

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

ISO 13485:2003 EN ISO 13485:2012

For the following activities

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

This certificate is valid from 12 July 2017 until 31 March 2019
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 31 March 2019

Issue 25. Certified since 23 June 1998



Authorised by

A handwritten signature in black ink, appearing to be 'J. [unclear]'. The signature is stylized and fluid.

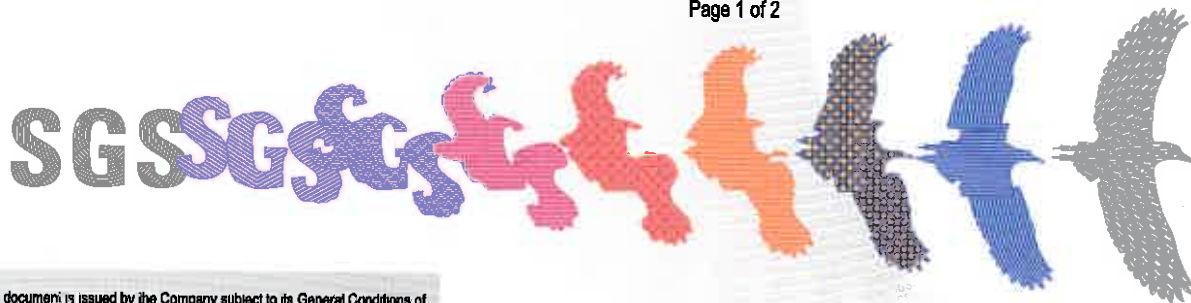
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Meditech Systems Ltd

ISO 13485:2003 EN ISO 13485:2012

Issue 25

Detailed scope

Design & Manufacture of :

- Sterile single use & non sterile electrosurgical cables**
- Sterile single use & non sterile gynaecological specula**
- Sterile single use & non sterile 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 & non sterile oropharyngeal and naso pharyngeal airways**
- Sterile single use & non sterile laryngoscope blades for intubation**
- 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, humidification and breathing system use**
- Non sterile air entrainment venturi jets, Non sterile nebulisers & 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**

Manufacture of :

- Sterile & non sterile reusable and single use laryngeal masks**
- Single use non-sterile oxygen masks, oxygen mask kits,**
nasal oxygen cannula, oxygen tubing
- Single use non-sterile nebuliser sets, Single use non-sterile venturi mask sets**

Distribution of:

- Anaesthesia and respiratory breathings sets & components, breathing filters, sterile instrument covers for scopes and cameras, electrosurgical devices, gynaecology devices, tracheostomy straps and fixation devices, pulse oximetry devices.**



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