

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 13485:2016 EN ISO 13485:2016

For the following activities

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

This certificate is valid from 23 June 2019 until 23 June 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 23 June 2022
Issue 30. Certified since 23 June 1998

Expiry date of last certificate: 23 June 2019
End date of last recertification audit: 05 April 2019

Authorised by

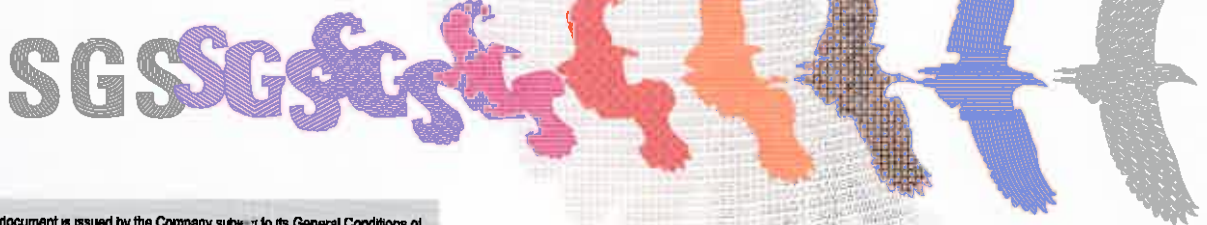


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Meditech Systems Ltd

ISO 13485:2016 EN ISO 13485:2016



Issue 30

Detailed scope

Design and manufacture of:

Non-sterile single-use cricothyroidotomy insufflation device.

Sterile, single-use cricothyroidotomy insufflation procedure sets.

Non-sterile single use air entrainment venturi jets.

Non-sterile, single use oxygen delivery masks, and mask sets.

Non-sterile, single use oxygen tubes, nasal cannulae and bite blocks.

Non-sterile, single use venturi jets & venturi mask sets.

Sterile single-use breathing systems.

Non-sterile single-use breathing systems.

Non-sterile re-useable breathing systems.

**Non-sterile single use breathing system filters
(HEPA filter, HME filter, Electrostatic filter, CO2 monitoring line filter).**

**Sterile single-use breathing system filters (HEPA filter, HME filter,
Electrostatic filter, CO2 monitoring line filter).**

Non-sterile single-use anaesthesia and respiratory components.

Non-sterile single-use, and reusable anaesthesia reservoir bags.

Non-sterile single-use PEEP valves and breathing system valves.

**Non-sterile, single-use aerosol tubes for oxygen, air,
humidification delivery, and gas scavenging.**

Sterile single- use insufflation tube and filter sets.

Sterile and non-sterile re-usable laryngeal masks.

Sterile and non-sterile single-use laryngeal masks.

**Sterile and non-sterile, single-use and re-useable electrosurgery.
monopolar and bipolar electrodes.**



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Meditech Systems Ltd

ISO 13485:2016 EN ISO 13485:2016

Issue 30

Detailed scope

Sterile single-use electrosurgery monopolar and bipolar forceps.

Sterile re-useable electrosurgery monopolar and bipolar forceps.

Non-sterile single-use monopolar and bipolar electrosurgery forceps.

Non-sterile re-useable electrosurgery monopolar and bipolar forceps.

Sterile single-use non-invasive medical instruments, and instrument sets.

Non-sterile single-use non-invasive medical instruments, and instrument sets.

Sterile single-use and reusable ENT speculae, and gynaecological Speculae.

**Non-sterile single-use and reusable ENT Speculae,
and gynaecological speculae.**

Sterile single-use oropharyngeal, nasopharyngeal airways, and bougies.

Non-sterile single use oropharyngeal, nasopharyngeal airways, and bougies.

Sterile single-use monopolar and bipolar, electrosurgical cables.

Non-sterile single-use monopolar and bipolar electrosurgical cables.

Non-sterile reusable monopolar and bipolar electrosurgical cables.

Sterile and non-sterile single-use electrosurgical cleaning scratch pads.

Non-sterile single-use laryngoscope blades for intubation.

Non-sterile single use, smoke evacuation tubing and filter sets.

Distribution of non-active medical devices and active medical devices (non-implantable) including anaesthesia and respiratory breathings sets and components, breathing filters, sterile instrument covers for scopes and cameras, electrosurgical monopolar and bipolar devices, non-sterile reusable ESU pencils, sterile single use ESU pencils, gynaecology devices (biopsy punches, colposcopy sets, trocars, HRT sets), single-use manual resuscitator sets, nebuliser chambers, humidification chambers, tracheostomy straps and fixation devices, pulse oximetry devices, sterile skin biopsy punches.



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