EC Certificate Full Quality Assurance System: Certificate GB19/964768

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 16 December 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 23 June 1998
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered GB/PC 08743

Authorised by

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Meditech Systems Ltd

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

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, and 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.
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.

Class I Sterile: Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:
Sterile single-use non-invasive medical instruments, and instrument sets.
Sterile single-use and re-usable ENT speculae, and gynaecological speculae.
Sterile single use oropharyngeal, nasopharyngeal airways, and bougies.
Sterile single-use monopolar and bipolar, electrosurgical cables.
Sterile and non-sterile single-use electrosurgical cleaning scratch pads.

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.