Certificate US11/81853

The management system of

Genicon Inc.

6869 Sta Point Court, Suite #114,
Winter Park, FL, 32792, United States

has been assessed and certified as meeting the requirements of

ISO 13485:2003
EN ISO 13485:2012

For the following activities

The design, manufacture, and distribution of Sterile Endoscopic Surgical Trocar Systems with sterile (single use) and non sterile (reusable) cannulae, Sterile Insufflation Needles and Sterile Disposable Gravity and Powered Suction Irrigation sets, and Sterile and non sterile Electrosurgical Instruments, and the distribution of Sterile Specimen Retrieval Bags, Non Sterile Irrigation Pumps, and Sterile and non sterile Ligation systems.

This certificate is valid from 4 September 2015 until 13 February 2017
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 1 October 2016
Issue 6. Certified since 13 February 2011

Authorised by

SGS United Kingdom Ltd Systems & Services Certification
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UKAS MANAGEMENT SYSTEMS
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SGS 13485-2 1114

EC Certificate Full Quality Assurance System: Certificate US11/81852

The management system of

Genicon Inc.

6869 Sta Point Court, Suite #114,
Winter Park, FL, 32792, United States

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

Sterile Endoscopic Surgical Trocar Systems with sterile (single use) and non-sterile (re-usable) cannulae, Sterile (single use) Gravity and Powered Suction Irrigation sets, Sterile (single use) Insufflation Needles, Sterile (single use) Specimen Retrieval Bags, Non Sterile (reusable) Irrigation Pumps, Sterile (single use) and Non Sterile (reusable) Ligation systems, Sterile (single use) laparoscopic monopolar graspers, dissectors and scissors and Non Sterile (reusable) electrocautery probes.

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.

This certificate is valid from 4 September 2015 until 13 February 2019
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 1 October 2016
Issue 7. Certified since 13 February 2011

Certification is based on reports numbered WW/ME 602703

Authorised by

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