EC Certificate Full Quality Assurance System: Certificate US11/81852

The management system of

Genicon Inc.

6869 Stapoint 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 cannulae, sterile single use gravity and powered irrigation sets, sterile single use insufflation needles, sterile single use specimen retrieval bags, sterile single use ligation systems, sterile single use laparoscopic monopolar and bipolar graspers, dissectors and scissors

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 20 April 2017 until 13 February 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 01 October 2019
Issue 9. Certified since 13 February 2011

Certification is based on reports numbered WWMC 602703

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
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SGS CE 02 0215

Certificate US11/81853

The management system of

Genicon Inc.

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

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The design, manufacture and distribution of sterile endoscopic surgical trocar systems with sterile single use cannulae, sterile single use gravity and powered irrigation sets, sterile single use insufflation needles, sterile single use specimen retrieval bags, sterile ligation systems, non-sterile reusable ligation clip appliers sterile and non-sterile electrosurgical instruments (probes), sterile single use laparoscopic monopolar and bipolar graspers, dissectors and scissors

This certificate is valid from 30 April 2018 until 31 March 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 01 October 2019
Issue 9. Certified since 13 February 2011

Authorised by

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