

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Efada Medical Industries Co. Ltd. (SUTCON SUTURES) Al-Jubaiha – Abdalla Al Louzy ST. Bld. No. 4 11941 Amman Jordan

has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition, for Class III products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 4006110/A

Original Approval: 13 September 2012

Current Certificate: 13 March 2019

Certificate Expiry: 12 May 2019

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE LRQ 4006110/A SCHEDULE

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Efada Medical Industries Co. Ltd. (SUTCON SUTURES)
Al-Jubaiha – Abdalla Al Louzy ST. Bld. No. 4
11941 Amman
Jordan

Class IIb Products

Non Absorbable Sutures: Sutcon® Silkpro Sutcon® Prylene Sutcon® Biolon

Schedule Issue: 02

Date of Schedule Issue: 13 March 2019

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