Pertificate of Registration



The Governing Board of Q.A. International Certification Limited hereby grants to:

SURGICON (PVT) LTD

Registration No.: QAIC / PK / 889 - B

(hereinafter called the Registered Company) the right to be listed in the Directory of Registered Companies in respect of the services listed below. These services shall be offered by the Registered Company at or from only the address given below in accordance with the quality management system in Compliance with the Requirements of **ISO 13485:2016.**

Address to which this Certificate refers:

P.O. Box: No: 244, Khadim Ali Road, Sialkot - Pakistan Approved Scope to which this Certificate refers:

Manufacture of Non-Active Surgical and Dental Instruments.

(Please note that the above scope represents the certified activity of the named organisation and as such, the organisation may undertake additional activities that are not covered under this certification).

Signed for and on behalf of the Board

CHIEF EXECUTIVE

SCHEME MANAGER

Certificate Issue Date: 1st April 2019 - Certificate Renewal Before: 31st March 2020 Date of Initial Registration: 28th April 2006 - Re-Certification Before: 31st March 2021

This Certificate of Registration is granted subject to the Regulations approved by the Board.

QA INTERNATIONAL

Q.A. International Certification Ltd. Dudley Court Dudley Road Darlington United Kingdom DL1 4GG

Tel: +44 (0)1325 384272 Fax: +44 (0)1325 480980 www.qai.co.uk







The use of the Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 046.

CERTIFICATE



Registration No. DCS/9479903

Application of Council Directive 93/42/EEC as updated directive 2007/47/EC for Class I Medical Devices

This is certifying that the products submitted are:

CLASS I MEDICAL DEVICES (Re-Useable, Non-Powered Surgical Instruments)

Manufactured By:

SURGICON LTD

P.O. Box: No. 244, Khadim Ali Road, Sialkot-Pakistan

Comply with the applicable requirements of the Directive 93/42/EEC as updated directive 2007/47/EC for Class I Medical Devices

The Technical file of the products have been assessed according to the procedure of Conformity Assessment described in the Annex -I, Annex VII.

Limitations:

The manufacturer must inform DCS of any substantial changes occurred in the Product or process in order to examine whether this certificate remains valid. Conformance to all the regulatory requirements is the sole responsibility of the manufacturer including the appointment of EU Authorized Representative and registration with concerned competent authority

CHAIRMAN

SCHEME MANAGER

Issue Date:

09 April, 2019

Expiry Date: 08 April, 2020

