Certificate 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
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EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL

C/ Horacio Lengo Nº18, CP29006 Málaga-Spain

NO. CMC/CE/2019/11062019-1

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative for

Annex I Medical Device Products with 1 page

MANUFACTURER BY COMPANY:
SURGICON (PVT) LTD
based on Khadim Ali Road Sialkot-Pakistan

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.
The products covered are in Annex I of 5 pages.

CE

Issued on: 11/03/2019

Expire on: 10/06/2020

Authorized Signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE

Annex I: List of Medical devices under the scope of certificate CMC/CE/2019/11062019-1

Class I non-sterile List of Instruments

- Diagnosis
- Scissors
- Supercuts Scissors
- Scissors with carbide tips
- Super Cut Titanium Nitride Scissors.
- Tweezers
- Forceps With tungsten Carbide inserts
- Haemostats
- Atraumatic Clamps
- Haemostats and dissecting
- Retractors
- Needle Holders
- Needle Holder with tungsten carbide inserts
- Vascular and tissue forceps
- Microsurgical instruments
- Sanction and flushing pipes, needles
- Self-retaining retractors
- Neurosurgery
- ENT Instruments
- Otology
- Rhinology
- Mouth, Jaws, and facial surgery
- Dental Instruments
- Tracheotomy
- Thorax, Lung
- Instruments for cardiovascular surgery
- Stomach, intestines rectum
- Liver, gall bladder, kidney
- Gynaecology, obstetrics
- Urology
- Ophthalmology
- Bone surgery, rongeurs