SURGIKARE

Directive 93/42/EEC

on medical devices, Annex V

Issue 1

Detailed scope

Sterile & Non sterile single use surgical Forceps,
Sterile & Non sterile single use surgical scissors,
Sterile & Non Sterile single use surgical Retractors,
Sterile & Non Sterile single use Surgical Tweezers,
Sterile & Non sterile single use surgical curettes,
Sterile & Non sterile single use Surgical Cannulas,
Sterile & Non sterile single use Suction Tubes,
Sterile & Non sterile Single use Needle Holders,
Sterile & Non sterile single use Bone Cutters,
Sterile & Non Sterile Single Use Surgical Probes,
Sterile & Non sterile single use Trocars,
Sterile & Non sterile single use Scalpel Handle without blade,
Sterile single use Catheters Used for Drainage of body Fluids

Annex V Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions

Sterile Single use Dental Scalars,
Sterile Single use Extracting Forceps,
Sterile Single use Mouth Gag,
Sterile single use Proto scopes,
Sterile Single Use Dental Syringes without needle,
Sterile Single use Dilators.
Sterile single use Vaginal Speculums,
Sterile single use Dental Elevator

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EC Certificate Production Quality Assurance System: Certificate PK19/818842593

The management system of

SURGIKARE

Toor Abad Daska Road Sialkot - Pakistan

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 29 June 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 29 June 2012
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered PK/LHR/ 221615

Authorised by

Pieter Weterings
Certification Manager

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HH 05 11

EC Certificate Full Quality Assurance System: Certificate PK19/818842594

The management system of

SURGIKARE

Toor Abad Daska Road, Sialkot, Pakistan

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 & Non-Sterile Single Use Bipolar Forceps with & Without Cables, Sterile & Non-Sterile Single Use Bipolar Electrodes, Non-Sterile Reusable Bipolar Forceps with & without cables, Non-Sterile Reusable Bipolar Electrodes.

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 16 December 2019 until 29 June 2023
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 25 November 2019
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered PK/LHR 221615

Authorised by

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