EC Certificate Full Quality Assurance System: Certificate CE 1639/MED 3658

The management system of

Surgical Specialties Mexico, S. DE R.L. DE C.V. also trading as Surgical Specialties Corporation

Corredor Tijuana-Rosarito 2000, #24702-B, Ejido Francisco Villa,
Tijuana, B.C., C.P., 22235, Mexico

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

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

This certificate is valid from 03 June 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 08 November 2001
and first certified by SGS Belgium NV since 16 December 2019

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered WW/MC 202106

Authorised by

SGS Belgium NV, Notified Body 1639
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Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

Sterile Sharpoint™, Sharpoint™PLUS, LOOK™, ExactEtch™, FSSB™, Onatec™ and Hu-Friedy™ Polypropylene Non-absorbable Surgical Sutures (Clear and Blue)

Sterile SHARPOINT™, SHARPOINT™ PLUS, LOOK™, PolySyn™, ExactEtch™, CyberTech™, FSSB™, Onatec™ and Hu-Friedy™Absorbable Polyglycolic Acid (PGA) Surgical Sutures

Sterile Sharpoint™ Polysyn FA™, Sharpoint™ PLUS Polysyn FA™, LOOK™ Polysyn FA™, ExactEtchTM, CyberTech™ and Hu-Friedy™

Fast Absorbing Polyglycolic Acid Synthetic Absorbable Sutures

Sterile Sharpoint™ Polyviolene™, LOOK™ Polyviolene, Sharpoint™ Plus Polyviolene, FSSB™ and Hu-Friedy™ Polyester Non-absorbable Braided Surgical Sutures (Green and White)

Sterile Sharpoint™Monoderm™ and Sharpoint™ Plus Monoderm™ glycolide / e-caprolactone synthetic absorbable surgical sutures. Quill™ Monoderm™ PGA-PCL Knotless Tissue-Closure Device, Stratafix™ Spiral PGA-PCL Knotless Tissue Control Device.

Sterile BioSentry™ Tract Sealant System.

Sharpoint™ PLUS Sterile PDO (Polydioxanone) Synthetic Monofilament Absorbable Sutures.

Sterile Quill™ SRS PDO (Polydioxanone) and Quill™ PDO (Polydioxanone) Knotless Tissue-Closure Devices and Stratafix™ Spiral PDO (Polydioxanone) Knotless Tissue Control Devices.

Sterile Nylon Sutures; Sterile Silk Sutures; Sterile Polypropylene Barbed Sutures, Sterile Bone Wax; Sterile PCL and Silicone Punctum Plugs; sterile microsurgical knives and surgical blades for general use, ophthalmic, and minimally invasive surgery.

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.

Additional facilities

1690 Brandywine, Chula Vista, CA, 91911, United States