

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

ISO 13485:2016 EN ISO 13485:2016

For the following activities

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

This certificate is valid from 08 November 2019 until 08 November 2022 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 08 November 2022 Issue 21. Certified since 08 November 2001

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

Authorised by

KC

HC SGS 13485 2016 0118 M2











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



ISO 13485:2016 EN ISO 13485:2016

Issue 21

Detailed scope

Design, manufacture and distribution of non-active implantable devices; Sterile Absorbable and non-absorbable sutures / needles; Sterile Absorbable and non-absorbable Knotless Tissue Closure Devices

sterile and non sterile microsurgical knives and surgical blades for general use, ophthalmic, and minimally invasive surgery

sterile bone wax; sterile non-absorbable and absorbable punctum plugs; Sterile Lung Tract Sealant System.

Contract manufacturer of non-sterile stainless-steel suture needles for surgical and specialty applications.

Additional facilities

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



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