



Certificate US06/67491

The management system of

Interplex Medical LLC

25 Whitney Drive
Milford, OH 45150, United States



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 27 February 2021 until 27 February 2024
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 3 December 2023.

Issue 13. Certified since 27 February 2006.

Authorised by

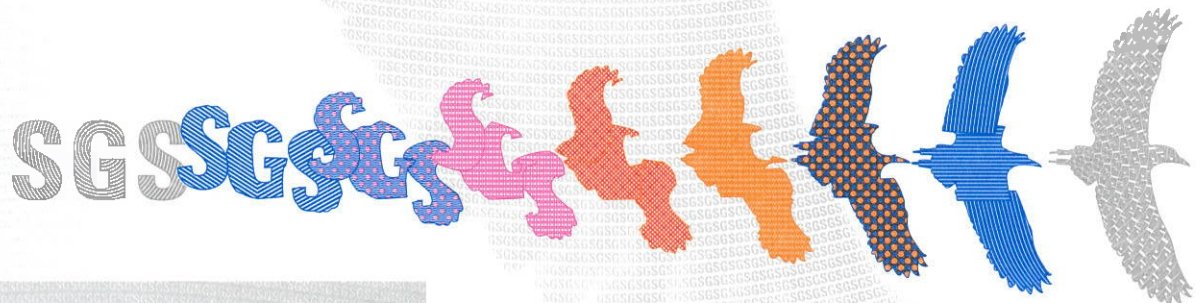
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HC SGS 13485 2016 0118 M2

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Interplex Medical LLC

ISO 13485:2016
EN ISO 13485:2016



Issue 13

Detailed scope:

Contract design and contract manufacturing of medical device components and assemblies for endoscopic suturing, stent delivery devices (tracheal, esophageal, biliary, cardiovascular, peripheral vascular, and gastric), valve stent delivery device, catheter based medical devices (vascular, balloon, and urinary), tissue apposition devices, grasper devices, endotracheal tube, laparoscopic devices, active surgical instrumentation, surgical instruments, blood collection devices, enteral feeding devices, vascular occlusion devices, polymer injection devices, gynecological devices, catheter cleaning device, urological devices, bariatric devices, percutaneous sensors, and cardiac defibrillation electrode pads, vein removal device, custom orthosis and portable i.v. fluid heater, vascular thrombus ablation device, vascular closure device, inflexible endoscopy devices, mechanical drug delivery pump, endoscopic snare device; orthopaedic discectomy device; catheters integrated with electrical wires/sensors, cardiac suction catheter, left ventricular assist device, guidewire locking and sealing device, vacuum assisted biopsy device, ultrasonic ablation catheter, pressure transducer stabilization device, pulmonary cancer diagnostic system, sub-dermal thermal imaging and measuring system, percutaneous arterial and venous embolectomy system, percutaneous peripheral vascular scoring device, percutaneous pulmonary antrum ablation device, percutaneous pericardial shunt device.



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