

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 2018 until 27 February 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 02 December 2020
Issue 12. Certified since 27 February 2006

Authorised by

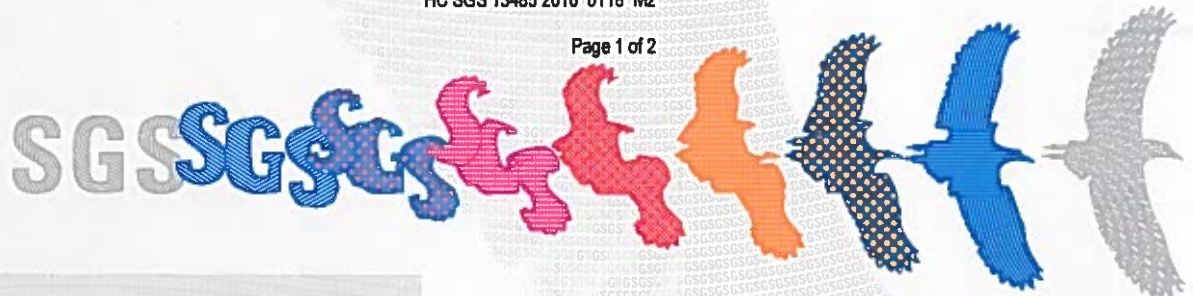


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Page 1 of 2



Interplex Medical LLC

ISO 13485:2016 EN ISO 13485:2016

Issue 12

Detailed scope



Contract design and contract manufacturing of medical devices including 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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