

# Finished Medical Device Assembly & Packaging



# A better approach. A better solution.®

QTS offers complete medical device outsourcing services including simple and complex assembly, packaging, validation, sterilization and testing services. We offer clients comprehensive outsourcing for project completion or an a la carte menu of services to suit your unique needs. Whether you have one project or multiple projects requiring medical device outsourcing, we are fully equipped and staffed to handle it.



**Package Design Expertise**



**Materials Sourcing**



**Engineering Validations**



**Label Development & Printing**



**Critical Inspection Services**



**Cleaning & Passivation**



**Device Assembly & Packaging**



**Sterilization Management**



**Lab Testing Services**



**Supply Chain Management**

# Critical End-of-Line Processing

QTS offers extensive medical device outsourcing experience and expertise. Our Minnesota facility provides sterile and non-sterile device assembly, kitting and packaging, with over 54,000 square feet of intuitively designed space including ISO Class 7 cleanrooms, engineering lab, and expansive warehouse for optimized process flow and complete traceability for your medical devices.



## QPOD®

Extend your organization with a QTS cross-functional, dedicated team of experts. Our QPOD team will focus on every detail of your project to make sure your device meets specifications, on time and on budget.

## Markets

- Orthopedic
- Spine
- Dental
- Neurology
- Cardiovascular
- Biologics
- Urology
- ENT
- Ophthalmic
- Pulmonary
- OB/GYN
- Gastroenterology

## Applications

- Implants
- Surgical Instruments
- Surgical Kits
- Combination Devices (Medical Device/Pharmaceutical)
- Pharmaceutical Kits
- Single-use, Bio-fluid Assemblies
- Accessory Devices
- Components
- Single-use Devices
- Sterile and Pre-sterile Devices

# Quality for Life

## Improving the quality of life for others.

Your medical device improves the lives of others, often times it saves lives. That's what drives us. We partner with you to impact lives and improve quality of life.

Our team of professionals is passionate about Quality — in every project, every process, every transaction and every audit. Because we understand that lives are at stake, we meticulously adhere to your requirements, all medical device standards and regulations.

We employ a robust Quality Management System, which includes electronic storage and change tracking of records, and also provides DMR and DHR traceability. We are responsive and intentional in regard to issues affecting the medical device industry such as RoHS, REACH and conflict minerals.



### **ISO 13485 Certified**

Medical Devices — Quality Management Systems — Requirements for regulatory purposes

### **FDA Registered**

CFR 21 Part 820  
Quality System Regulation – Medical Devices

### **ISO Class 7 Cleanrooms**

### **J-PMDA**

Japanese Manufacturing Certification

### **State of Minnesota Board of Pharmacy Manufacturers License**



## **QSEAL® Pre-Validated Medical Packaging**

Validating a package that is compliant to the FDA and ISO 11607 requirements can be a time consuming and expensive obstacle to getting your new medical device on the market. Designed and developed by QTS exclusively for our customers, the innovative QSEAL Pre-Validated Medical Packaging Solution streamlines and accelerates your go-to-market process. Instead of starting from scratch, you can choose rigid and flexible packaging options that include seal validations, five-year accelerated aging, and have already been validated for Gamma, Ethylene Oxide and Electron Beam sterilization processing.

# Cretex Medical

Cretex Medical is a growing family of companies that specializes in medical device contract manufacturing. Private ownership, a long-term perspective and a strong financial portfolio allow us to invest in the leading-edge technology and engineering know-how required to meet today's launch-critical timelines with confidence.

Whether you are a Fortune 500 medical technology stalwart or a promising startup, you can depend on our integrated approach to provide new efficiencies at every turn. When speed-to-market, quality compliance and design for manufacturability expertise are paramount to your program, there is no company more capable or more responsive than Cretex Medical.



[www.cretexmedical.com](http://www.cretexmedical.com)



[www.rmsmachining.com](http://www.rmsmachining.com)

Contract manufacturing of medical devices and assemblies using state-of-the-art machining.



[www.rmssurgical.com](http://www.rmssurgical.com)

Custom instrument manufacturing combined with design and fabrication of sterilization cases and trays. Focus on fast turnaround of prototype and production requirements.



[www.junopacific.com](http://www.junopacific.com)

Medical device design, contract manufacturing and assembly, specializing in micro-molding, insert molding and multi-shot injection molding technology.



[www.meiertool.com](http://www.meiertool.com)

Custom metal stamping, specializing in small and miniature metal-formed components and assemblies.



[www.spectralytics.com](http://www.spectralytics.com)

Contract laser micromachining and assembly of implantable devices and components for medical device manufacturers.



[www.qtspackage.com](http://www.qtspackage.com)

Medical device outsourcing services including cleanroom assembly, kitting, packaging, labeling, validations, inspection, cleaning, sterilization and supply chain management.

## Using QSEAL you can build a complete packaging system including:

- PETG trays
- Tyvek® lids
- Poly/Tyvek® pouches
- Nylon/Tyvek® pouches
- Foil/Foil pouches
- Customized tray inserts
- Standard label stock
- IFU paper stock
- SBS shelf boxes
- Foam protection
- Protective packaging sleeves



# Quality Tech Services, LLC

Our array of services spans the entire process cycle from package configuration through supply chain management. We tailor our offerings to ensure each client receives the best value by balancing costs and quality with time to market. Our deep industry knowledge and years of experience enable us to deliver an innovative total solution that moves you to market faster and more cost-effectively.

Contact us today to learn how QTS can help with your next project.



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[qtspackage.com](http://qtspackage.com)

QTS is part of the Cretex Medical Family of Companies.



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