

# Medical Devices & Instrumentation



## Class I, II and III Medical Devices and Assembly Processes:

Parker's Medical Systems Division is a single source FDA registered and ISO 13485 certified finished medical device contract manufacturing firm.

We offer single use devices, reusable devices, instrumentation, and invitro diagnostic assembly, testing, packaging and sterilization.



## Class I, II and III Medical Devices:

- Critical Care
- Cardiology
- Operating Room
- Cardiac Cath Lab
- Respiratory Therapy
- Emergency Room
- Neurology
- Oncology
- Labor and Delivery
- Chronic Care
- Clinical Laboratory
- Sleep Labs
- Audiology

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## Medical Instrumentation:

Parker's Medical Systems Division also offers highly responsive assembly and testing of medical instrumentation ranging from relatively simple electro-mechanical devices to highly complex multi-technology integrated systems.



ENGINEERING YOUR SUCCESS.

### Assembly Processes Include:

- Ultra-precision, precision & standard assembly
- Electro-mechanical assembly
- Catheter assembly
- Nitinol wire forming
- Thermal tip forming
- Solvent & cyanoacrylate bonding
- UV adhesive, epoxy & polymer adhesive bonding
- P.C. board assembly
- Precision & standard soldering
- Fiberoptic processing including; lens forming & polishing, bonding, gapping, cladding, polishing & fiber pyrolyzing
- Flow, leak & tensile testing
- Glass forming
- Gold wire bonding
- Controlled siliconizing & silicone dispersion coating
- Hermetic seam welding
- Electro-static bonding
- Ultra-sonic welding
- Thermal welding & staking
- Micro riveting
- Micro arc welding
- Ultra-sonic cleaning
- Automatic & semi-automatic software controlled testing
- Electro-mechanical testing
- Packaging including pouch, pre formed trays & form-filled-seal
- Sterilization including ethylene oxide & irradiation

### Front End Design Assistance:

- Design for manufacturability analysis
- Plastic part design
- Material selection
- Rapid prototyping
- Prototype injection molds for low cost design verification
- Sterile package design
- Shelf and shipping box design and configuration

### Process Development and Validation:

- Assembly process definition and design
- Test procedure definition and design
- Tooling and fixture design and fabrication
- Equipment validations including I/Q, O/Q and P/Q
- Design of experiment
- Validation protocol development, testing and reports
- Sterile package seal strength characterization
- Sterilization validation

- Accelerated age studies
- Transit testing
- Biocompatibility testing

### Product Manufacturing:

- Full lot control and/or serialization
- In-process and final quality assurance
- Sterile packaging in all standard formats
- Sterilization coordination including QDAs and annual EO revalidations

### Device History Record/Master Record:

- Complete device manufacturing documentation
- Complete work order history
- Full lot control



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