

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.



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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

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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- The user, through its own analysis and testing, is solely responsible for making the final selection of the system and components and assuring that all performance, endurance, maintenance, safety and warning requirements of the application are met. The user must analyze all aspects of the application, follow applicable industry standards, and follow the information concerning the product in the current product catalog and in any other materials provided from Parker or its subsidiaries or authorized distributors.

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