



## Medical Device Manufacturing & Engineering



## TRICOR Systems Inc.

TRICOR Systems Inc., winner of the 2008 Medical Design Excellence Award, is an FDA registered, ISO 9001:2015 and ISO 13485:2016 medical manufacturer and design facility. Founded in 1976, TRICOR has successfully provided high-quality products and services to the medical, military and industrial marketplace.

TRICOR possesses the expertise to design, develop, validate, and manufacture Class I, II and III electronic medical devices under one roof. Whether you are looking for a complete turnkey solution, design review for manufacturability or just supplementing your internal capabilities, TRICOR has the background and flexibility to meet your requirements. TRICOR offers the opportunity to confidently outsource your project needs

## Contract Manufacturing Capabilities

TRICOR's Contract Manufacturing capability is structured to produce a wide variety of products for its customers. TRICOR can manufacture small quantities of prototype and pre-production units to large quantities such as the 50,000+ unit/year rate achieved on the Wand System. Our experience with Class I, II and III devices minimizes problems and facilitates quicker product turns. Changes or product updates are also streamlined due to TRICOR's in-house engineering staff.

## Summary List

- Class I, II and III Medical Device Manufacturer
- Electronic and Electro-Mechanical Contract Manufacturer
- Assembly and precision hand or machine soldering of printed wiring boards
- Thru Hole or SMT assembly
- Complete panel and chassis wiring
- Cable harness fabrication
- Mechanical assembly
- Test: Qualification through Burn-in
- Full service device packaging
- Drop shipping
- Repair depot
- Device History Record Generation
- ITAR Registered
- Quality Management System (QMS):
  - o Certified to ISO 9001:2015, ISO 13485:2016 and AS9100D
  - o Compliant to GMP
  - o Compliant to FDA Quality System Regulation (QSRs) 21 CFR 820



## Contract Engineering Capabilities

TRICOR's Engineering provides outstanding capabilities not found in many companies. From the design of simple fixtures to complete systems, the attention given to performance, reliability and quality does not vary. TRICOR's experienced engineers are proficient in both hardware and software design.

Electrical/Mechanical/Industrial Engineering tools/aids: The latest state-of-the-art schematic capture and PCB layout tools from Mentor Graphics are used on all electrical design activities. To develop the highest quality mechanical items, TRICOR utilizes both 2D and the advanced 3D solid modeling tools offered by Solidworks.

As products become more sophisticated, medical device performance is highly dependent on reliable, verifiable and maintainable software. By utilizing current development tools, coupled with a controlled design structure, the customer is ensured product and regulatory specifications are satisfied.

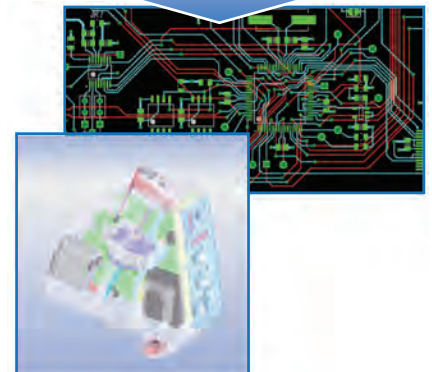
### Summary List

- Engineering and Manufacturing system certified to ISO 9001:2015, ISO 13485:2016 and ISO AS9100D
- Safety Requirements to IEC 60601 3rd edition or UL 2601 and
- PMA & 510k submission assistance
- Software Verification and Validation
- FMEA
- Product and Design Validation
- Risk Analysis
- Perform hardware/software trade-offs in order to achieve desired goal at minimum cost
- Execute the electrical and mechanical designs needed for hardware fabrication
- Compose and debug all embedded and PC software
- Breadboard and test various design approaches
- Layout, verify, and tool required printed circuit boards
- Provide complete manufacturing documentation package
- Procure/Fabricate/Test and Debug subassemblies and systems
- Support Manual Publication, e.g., theory of operation and troubleshooting procedures

### Design



### Develop



### Manufacture





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