

Universal Electronics, Inc. is a full-service contract manufacturer specializing in the manufacturing and support of complex electronic medical devices. Since 1980, our company has specialized in this uniquely demanding field and has invested considerable resources in order to become your premier medical electronics solution.

Universal Electronics has extensive experience in medical device manufacturing. We have built hundreds of unique medical device assemblies and shipped hundreds of thousands of medical devices, ranging from printed circuit board assemblies to complete “box build” assemblies.

### **Quality Assurance Management Systems:**

- ISO 13485:2003 in Whitewater, WI
  - \* Quality management system meets health Canada CMDCAS requirements for Canadian class II, III and IV devices.
  - \* Quality management system meets compliance requirements for the European MDD and IVDD directives.
- ISO 9001:2008 in Whitewater and East Troy, WI
- FDA class I, II and III products
- FDA audited quality management system that is 21CFR 820 GMP/QSR compliant
- IPC-A-610 “Latest Revision”, class I, II and III
- Recognized manufacturer to domestic and international safety standards
- Full lot traceability for products and process non-conformances
- Comprehensive device history record archival process
- Comprehensive risk management process for manufactured products
- Design for manufacturability (DFM) review early in the fulfillment cycle





"DEDICATED TO CUSTOMER SATISFACTION"

**MEDICAL**

**Manufacturing:**

- PCB manufacturing (SMT and PTH)
- Sub assembly and full box build
- Multiple manufacturing facilities
- Component traceability
- Comprehensive materials management
- Program management teams
- Device history file
- QSR compliant
- Sustaining services and repair depot
- Design for manufacturability (DFM)

**Test:**

- Test strategy development
- Design for test (DFT)
- Functional electronic automated test system (FEATS)
- In-circuit test (ICT)
- Flying Probe testing
- X-ray for process validation
- Automated optical inspection (AOI)
- Burn in and life testing programs

**Product Experience:**

- Blood gas monitoring
- Respiratory care
- RF patient alarm systems
- Pain management systems
- Telemedicine
- EKG monitoring
- Liquid handling equipment
- Blood pressure monitoring
- Imaging systems and much more!

Contact us to learn how our experienced team can help with your next medical device project.



**Universal Electronics, Inc.**

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