

# LEADERSHIP IN ELECTRONIC PRODUCT DESIGN

Our Sanmina, Huntsville Medical Product Design organization develops a broad range of products, with a specialty in medical devices and medical electronics for many of the world's leading Original Equipment Manufacturers (OEMs). With an ISO 13485 design certification, we specialize in product architecture, systems engineering, circuit design, fluidics, mechanical engineering and test engineering. Our extensive Design History Files capability includes requirements management, risk management and full design controls, enabling us to provide turnkey designs and services. We completely validate processes and tools, while using a sophisticated quality system to ensure regulatory and QSR compliance. Our robust medical device supply chain includes supplier qualification and ongoing supply chain management. Sanmina Huntsville optimizes designs for reliability, manufacturability and service, while customers retain all rights to product IP.

To learn more, visit www.sanmina.com.



Two medical products, redesigned by Sanmina for significant cost reduction and improved reliability.

## MANUFACTURING CAPABILITIES

- Full-Service Medical Device Assembly and Test
- Electronic Device History Records (DHRs)
- Complex Systems, Electromechanical Devices, Sensors and User Interfaces
- Precision Automated SMT Assembly: from 0201 to Flip Chip
- System-Level Integration, Box Build and Test
- Value-Add/Value Engineering (VA/VE) Services

#### **TESTING CAPABILITIES**

- · Verification and Validation Testing
- Automated Production Test Systems for Complex Products
- Turnkey Test Development: End-to-End Test, Functional and Structural
- 2D/3D X-ray, Flying Probe (FP),
   In-Circuit Test (ICT), Advanced Optical
   Inspection (AOI) and PC JTAG/Boundary Scan
- Environmental Stress Test (EST)/Burn-In Facilities

#### **ENGINEERING CAPABILITIES**

- Systems Engineering & Systems Architecture
- Requirements Management, Risk Management
- Verification Testing, Safety & Agency Certifications
- Electrical, Mechanical and Software Design
- Quality Engineering
- Design Controls: Fully Documented Process Compliant with the QSR and ISO 13485
- Compliance with IEC 60601-1 3rd Edition
- ISO 14971 for Risk Management Process
- IEC 62304:2006 for Medical Device Software

# **LOGISTICS SERVICES**

- Direct Order Fulfillment
- Build-to-Order (BTO)/Configure-to-Order (CTO)

## **CERTIFICATIONS**

• ISO 13485-2003

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