



Medical Manufacturing Solutions





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CTS Electronics Manufacturing Solutions is an experienced provider of medical implantable devices and equipment to customers worldwide. Our familiarity with the unique requirements of the medical sector allows us to develop expert solutions for OEMs seeking a reliable and credible partner for their critical product manufacturing.

New Product Introduction (NPI)

We understand how time-critical the product development and qualification phase can be for a medical OEM – and how much more complex and risky it is than introducing a standard electronics product to the market. Our experience and skilled program management personnel work closely with the customer to minimize the ‘scope creep’ that often occurs and to ensure that the product reaches the market as smoothly as possible.

Medical Product Development & NPI Services

- ⦿ Local, Experienced Cross-Functional Medical Market Program Teams
- ⦿ Project Management Approach
- ⦿ Design Ratification:
 - ⦿ Design for Manufacturing & Assembly (DFMA)
 - ⦿ Design for Test (DFT) & Parallel Test Development
 - ⦿ Failure Mode Effect Analysis (FMEA)
- ⦿ Flying Probe Testing & Automated Optical Inspection
- ⦿ Working Knowledge of FDA Qualification Process & Documentation Requirements
- ⦿ Ability to Introduce Products Locally & Transition to Other Facilities for Volume

Volume Manufacturing for Medical Customers

Ramping to volume can be a complex process. Whether transferring products from the customer to CTS, or between CTS locations, CTS employs a robust, documented product transfer process that renders seamless product transition to the customer and minimizes the delay in delivering products to the market. If a customer wishes to transfer certified lines to CTS for product manufacture, CTS has experience in managing these transfers. We also employ rigorous process capabilities and controls: installation, operation, equipment and performance qualifications or IQ, OQ, EQ and PQ, as they are commonly known.

Medical Product Manufacturing & Services

CTS’ worldwide operations are specially equipped to support medical device manufacturing. Our facilities hold ISO13485 and ISO9001: 2000 accreditations and have program teams experienced in on-site medical device manufacturing for focused customer support. Manufacturing operations focus on providing flexible and agile services to customers, underpinned by lean manufacturing methodologies, program management support and focus on quality assurance throughout the program lifecycle.



Products & Services

Products

- ⦿ PCB Assembly:
 - ⦿ Complex Technologies
 - ⦿ Small-Form Devices
 - ⦿ Exotic Materials & Finishes
 - ⦿ Press-Fit SMT Backplane Assembly
- ⦿ Medical High Level Assembly (Box Build):
 - ⦿ Plastics Integration
 - ⦿ Sheet Metal Integration
 - ⦿ Full System Configuration & Test
 - ⦿ Experience of Medical Box Build

Specialist Medical Services

- ⦿ Class 10,000 Clean Room Manufacturing
- ⦿ Medical Documentation Control
- ⦿ Lot Traceability & First Article Inspection
- ⦿ Traceability & Record Retention

Global Manufacturing Services

- ⦿ Global Manufacturing Opportunities – North America, Europe, Asia
- ⦿ Design & Engineering Services
- ⦿ Lean Manufacturing Methodologies
- ⦿ Program Management
- ⦿ Supply Chain Management
- ⦿ Product Transfer Management

Test Engineering

- ⦿ Manual Defect Analysis
- ⦿ In-Circuit Test
- ⦿ Functional Test
- ⦿ Final Assembly Test
- ⦿ Hi-Pot Test
- ⦿ Audit Testing on Complete Integrated Systems
- ⦿ Accelerated Lifecycle Testing (Burn-In)
- ⦿ Environmental Test Chambers
- ⦿ HALT & HASS Testing for High Complexity Applications
- ⦿ Flying Probe Test Applications

Quality & Regulatory

- ⦿ ISO13485 Global Facilities
- ⦿ ISO9001-2000
- ⦿ IPC Class III Workmanship Standards
- ⦿ FDA Quality Systems Compliance
- ⦿ Operator Training to GMP 21 CFR Part 820

Medical Device Experience

CTS has broad experience in manufacturing medical devices and equipment. Below are some of the applications supported by our facilities:

- ⦿ Pain Management Systems
- ⦿ Heart Defibrillation
- ⦿ Spinal Implants for Stroke Therapy
- ⦿ Blood Pressure Regulators
- ⦿ Blood Gas Analysis Equipment
- ⦿ Blood Glucose Monitoring
- ⦿ Ophthalmology Devices
- ⦿ Audiology Equipment



www.ctscorp.com/ems

ISO9001 – 2000 • ISO13485 • ISO14001 • FDA Compliance
GMP 21CFR Part 820

CTS Manufacturing:

Moorpark CA, USA
Santa Clara CA, USA
Matamoros, Mexico
Glasgow, Scotland
Londonderry, NH, USA
Tianjin, China
Singapore
Bangkok, Thailand

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