

Medical Device Manufacturing



Precision stamping, forming, welding, and assembly for medical device components — backed by ISO 13485–certified quality systems, full lot traceability, and U.S. –based manufacturing support.

When medical device components require precision, repeatability, and documentation, ACM gives OEMs a manufacturing partner built for complex, production-ready programs. From surgical instrument components to diagnostic device assemblies, ACM supports high-volume manufacturing with the engineering discipline and quality controls medical programs demand.

Certification	ISO 13485
Facility	Phillipsburg, NJ — USA
Traceability	Full lot and material certification support
Experience	30+ years / 10B+ parts produced
Core Capabilities	Precision stamping, injection molding, forming, welding, assembly

Capability Snapshot

ACM supports medical device component programs that require tight tolerances, repeatable production, and documented process control.

Capability	Details
Materials	Stainless steel, titanium alloys, and plastics, depending on program requirements
Typical Tolerance	0.0005 → 0.005"
Production Speed	Part or Assembly-dependent — up to 500 parts/minute
Secondary Operations	Laser welding, ultrasonic welding and cleaning, and assembly

Medical device programs are rarely just about making the part. They are about producing the part consistently, documenting the process clearly, and supporting the requirements that come with regulated manufacturing.



Why Medical OEMs Work With ACM

- ✓ Design freeze isn't the finish line — ACM's process validation and documentation practices are built to support the full path from design control through production.
- ✓ Every lot has to be traceable, not just the ones that go wrong — ACM's traceability process covers every shipment, not just flagged ones.
- ✓ Biocompatible and tight-tolerance materials require process discipline most contract shops don't carry — ACM's passivation, laser welding, and ultrasonic cleaning capabilities are built around medical-grade requirements.
- ✓ Regulatory submissions depend on documentation you can actually produce on request — ACM's quality records are maintained to support audits, not reconstructed after the fact.
- ✓ Manufacturing stays U.S. -based, supporting supply chain confidence for regulated medical programs.

Quality & Compliance

For medical device manufacturing, quality cannot be treated as a final inspection step. It has to be built into the production process.

ACM supports medical device programs with:

ISO 13485:2016 certified quality systems

Full lot traceability from raw material heat/lot number through finished part shipment

Material certifications and inspection reports retained to support regulatory documentation

Controlled-environment assembly available for select programs

Quality documentation reviewed against program-specific requirements, not a generic template

ACM is a fit for medical device components that require precision manufacturing, repeatability, and documentation.



Representative Part Categories

Category	Example Applications
Surgical Instrument Components	Precision stamped and formed components for reusable and single-use instruments
Device Housings	Formed and welded housings or injection moldings for diagnostic and monitoring equipment
Contacts and Springs	Precision springs and electrical contacts for diagnostic assemblies
Small Precision Assemblies	Multi-step manufactured components requiring forming, welding, cleaning, or assembly

Before You Submit an RFQ

To help ACM evaluate your program efficiently, include as much of the following as possible:

- ✓ Part drawing with CTQ criteria
- ✓ Material specification
- ✓ Biocompatibility requirements, if applicable
- ✓ Regulatory class, if known
- ✓ Sterilization method, if required
- ✓ Annual volume or production forecast
- ✓ Target launch, validation, or submission date
- ✓ Secondary operation requirements, such as welding, cleaning, passivation, or assembly

Bringing a Medical Device Program to ACM?

Send your print, material spec, regulatory class if known, and production requirements. ACM will review feasibility, documentation needs, and manufacturing fit before recommending a path forward.

Start an RFQ. Contact Sales@bihler.com