

Medical Devices Overview

For more than two decades, Boston Engineering has partnered with medical clients to improve the way that people work and live.

Boston Engineering provides product design and engineering consulting from concept development through commercialization.

We combine innovative thinking with the technical experience and the regulatory insights required to advance medical research, diagnostics, and treatments from the surgical suite to e-health.

Certified for ISO 9001 and ISO 13485 standards, Boston Engineering applies its phase-gate development process to:

- Accelerate new product development
- Mitigate risk
- Optimize design for manufacturability and assembly
- Comply with stringent regulatory requirements
- Accelerate time to market

Innovation Centers of Excellence (COEs) for Medical Devices





The Boston Engineering Advantage

- **Accelerate New Product Development:** Boston Engineering translates groundbreaking ideas into successful products, and has a proven track record helping clients bring cleared/approved products to market.
- **Mitigate Risk:** Extensive research and feasibility analysis early in the innovation process eliminates problems later in the development cycle. Boston Engineering addresses risk for both the product and the project.
- **Cut Costs:** We identify opportunities to reduce production costs throughout the product development process. For current products, we address the supply chain and regulatory issues associated with obsolescence to extend the product lifecycle and to trim costs.
- **Apply Compliance Expertise:** Boston Engineering provides the industry knowledge to minimize the time and expense associated with global regulatory requirements (e.g., US FDA Clearance, EU CE Mark, etc.).

Quality Management

Our quality management system (QMS) ensures compliance throughout each development phase.

Using our certified design control procedures, we collaborate with our customers to create and maintain the design history file (DHF) documentation required for rigorous compliance reviews.



Medical Expertise

We drive innovation throughout the medical sector, including:

- Biomedical
- Diagnostics
- E-health / connected care
- Laboratory research
- Medical devices
- Surgical instruments
- Therapeutics

About Boston Engineering

Boston Engineering provides product design and engineering consulting from concept through commercialization and connectivity. Boston Engineering is also the Northeast's largest PTC software reseller and is a ThingWorx IoT partner.

Certified for ISO 9001 and ISO 13485, the company's industry expertise includes commercial, defense, and medical. Founded in 1995, Boston Engineering is headquartered in Waltham, Mass.



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