

Testing

& EVALUATION SERVICES

- TEST EQUIPMENT
- SILICONE VESSELS
- SIMULATION SOLUTIONS
- CONSULTING SERVICES

BDC LABORATORIES

A Tentamus Company



"Using a mix of their tried-and-true systems and new electromechanical components, BDC produced test equipment that precisely met our needs. In addition to being on scope and schedule, I was impressed by the thought that Ben McCloskey put into the GUI and overall usability of the system. He and Craig were a pleasure to work with."

— Test Equipment

Working with the BDC Laboratories team is always a great experience. BDC's level of expertise and knowledge in the areas stent graft testing and hemodynamics are truly invaluable. Their range of capabilities from mock vessels, testing services and equipment design makes them a full service vendor that makes for seamless execution. BDC Laboratories capabilities and expertise has allowed me to accelerate my project and gain a greater understanding of our product."

— Testing Services

"We recently purchased the LDT-1500 linear fatigue test machine from BDC Labs. Both the machine and the level of technical support were excellent. With a shorter lead time and a price that was a fraction of the cost of competitive machines from other vendors, we remain very pleased with our purchase."

— Test Equipment

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CMDC
CARDIOMED DEVICE CONSULTANTS
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FROM CONCEPT TO MARKET

Serving medical device manufacturers worldwide, BDC Laboratories and CardioMed Device Consultants deliver comprehensive support across the total product lifecycle of Class II and III medical devices.

UNIQUELY COMPREHENSIVE SERVICE

Medical device manufacturers worldwide have relied on BDC Laboratories and CardioMed Device Consultants to navigate every stage of the product lifecycle, from concept through device approval and market launch. Few partners can offer this breadth of regulatory and testing support under one roof. With more than 200 years of combined experience, our teams support medical device development with a rare pairing of technical precision and regulatory insight — all under one coordinated engagement.

Our collaboration means: We work with your team throughout the full product development cycle.

From early design through submission, CardioMed leads the regulatory consulting and develops a testing approach and plan, drawing on a team of former FDA employees who know the ins and outs of the approval process.

BDC works from initial feasibility testing through regulatory submission and into production tests. Active participation in AAMI, ISO, and ASTM standards committees gives the BDC team unique insight into developing plans and protocols for FDA and CE Mark submissions.

WE BECOME AN EXTENSION OF YOUR TEAM

CardioMed + BDC acts as a force multiplier. With large organizations, this means we work with in-house regulatory and R&D teams. With small companies and startups, CardioMed + BDC become the team that takes care of regulatory strategy and testing services.

Our combined expertise and experience make us agile in bringing novel technologies to market.

Novel devices carry distinct regulatory complexity and can take three to ten years to reach market depending on risk class and device classification. You need a team who has seen it all to help guide you through this complex process.

We serve a wide range of customers, from start-ups to multinational corporations.

Organizations with vastly different resources have different requirements for regulations and testing support. We understand the obstacles you will face and the best ways to overcome them.

COMPLEMENTARY EXPERTISE

CardioMed Device Consultants

- FDA regulatory strategy and submission support
- Guidance on FDA preclinical testing requirements (Class II and Class III)
- Expertise from former FDA CDRH reviewers
- Specialized support for startups and international manufacturers
- Broad spectrum of technologies, including endovascular devices and digital health solutions

BDC Laboratories

- Mechanical and functional device testing
- Regulatory submission testing (Class II and III)
- Custom test protocols, equipment and simulation systems
- Comprehensive device testing reports
- GLP compliant
- ISO/IEC 17025 accredited

The Ultimate Device Evaluation Partner



The BDC Laboratories' team has over 40 years of experience in medical device research, development, and design verification testing. Our focus is on functional, engineering based assessment of medical devices, including Class 2 and Class 3 implants.

BDC personnel actively participate in The American Association of Medical Instrumentation (AAMI), the International Standards Organization (ISO) and ASTM standard committees. As participants on these committees for structural heart, cardiac and endovascular technologies, the BDC team have a unique understanding of developing medical device testing and verification plans, along with the associated protocols and methods to support FDA, Notified Body and regulatory submissions worldwide. From this unique expertise, and leveraging the multiple divisions of BDC (testing services, test equipment, silicone vessels & anatomical models and simulation solutions), our team can truly become your comprehensive device evaluation and testing partner, at both the R&D and design verification stages of device development. BDC can provide support and services in:

- Risk assessment and device evaluation strategies
- Novel test method development and validation
- Tracking pathway design and manufacturing
- Test fixture design and manufacturing
- Device testing and evaluation, both acute bench testing and durability/fatigue studies
- Silicone vessel and anatomical model design and manufacturing
- Custom test system design and manufacturing

ISO/IEC 17025:2017 Accredited

Recognizing our responsibility as a service provider to the medical device industry, BDC Laboratories is committed to providing the highest level of quality and technical accuracy for all our test services and product offerings. In alignment with this philosophy, BDC is an ISO/IEC 17025:2017 Accredited testing laboratory. ISO/IEC 17025:2017 is an internationally recognized standard that outlines the general requirements for the competence of testing laboratories. By working with BDC as an Accredited laboratory, the regulatory authorities immediately appreciate the superior quality management system associated with your testing program and test data.

PJLA Testing

Accreditation #87132

Technologies Routinely Evaluated

- Heart Valves
- Vascular Grafts
- Heart Valve Repair Devices
- Catheters
- Stent Grafts
- Vena Cava Filters
- Stents
- Guidewires
- Cardiac Occluders
- Dilators

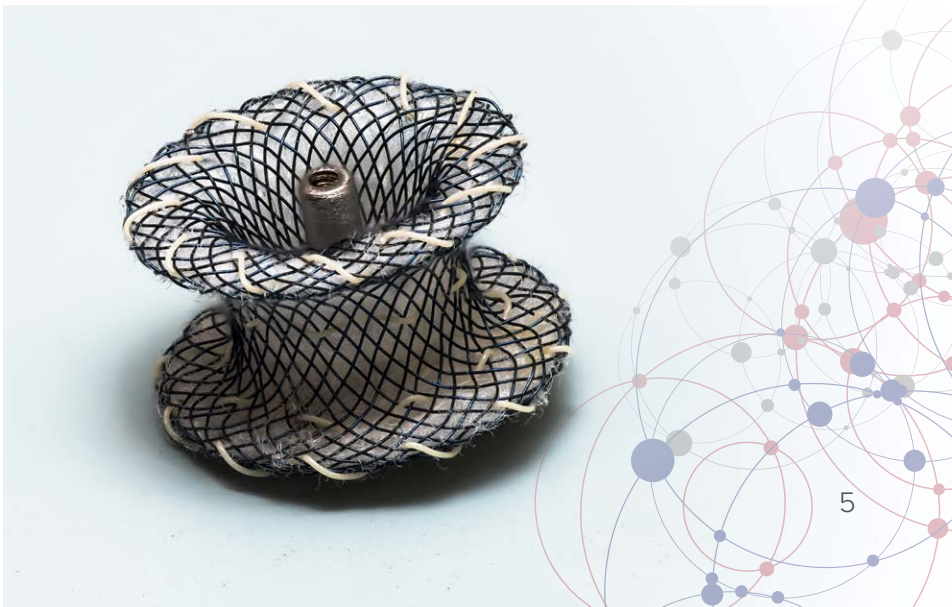
All-Inclusive Regulatory Programs

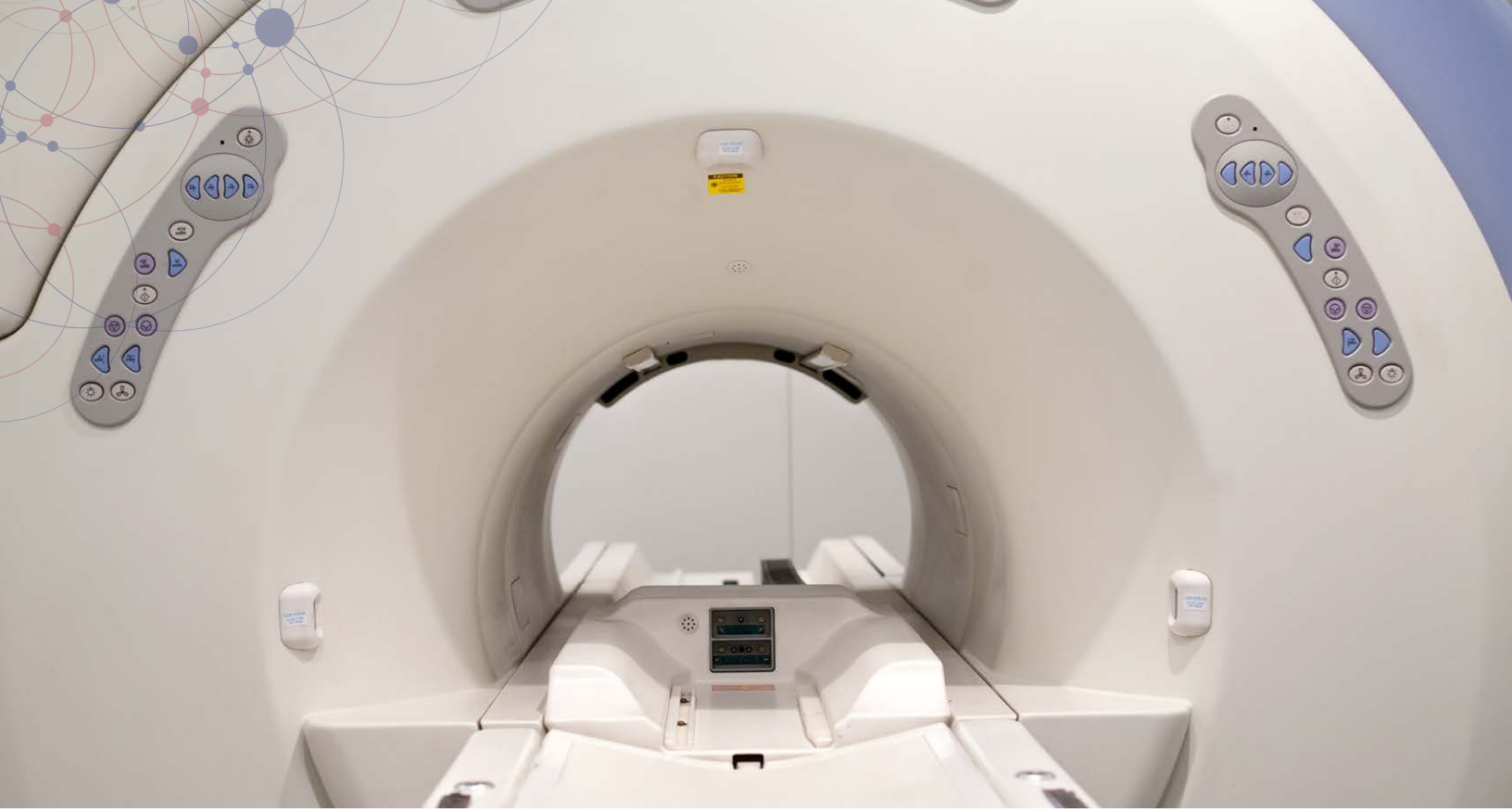
BDC Laboratories can evaluate all aspects of your medical device, providing compressive test programs as outlined in ISO standards and FDA guidance documents. This rare capability streamlines your device's testing and evaluation program and yields a quicker time to regulatory submission and regulatory approval.

- ISO 25539 (all parts)
- ISO 5840 (all parts)
- ISO 5910
- ISO 7198
- ISO 10555 (all parts)
- ISO 11070
- FDA Guidance for MRI Labeling
- FDA Stent Guidance
- FDA Guidewire Guidance
- FDA PTCA Catheter Guidance
- FDA Hemodialysis Catheter Guidance
- FDA Guidance for Intervascular Catheters

Visit **BDCLabs.com** or contact us at **303.456.4665** to fully appreciate all the ISO, ASTM, and FDA standards we can execute







Beyond Cardiovascular

As an ever-expanding organization focused on the evaluation of Class II and Class III medical devices, BDC Laboratories offers our testing services for technologies beyond structural heart, cardiovascular and endovascular devices.

SELECTED UNIVERSAL DEVICE TEST METHODS

- MRI Compatibility Evaluation, including Numerical Simulation
- Electrochemical Corrosion
- Material Fatigue (S-N) Characterization
- Coating Integrity & Acute Particulate Characterization

> *"We have used BDC testing services, purchased their test equipment and their silicone mock vessels, all of which have met or exceeded our expectations, been cost effective and delivered in a very timely manner. BDC's knowledgebase surrounding the medical device development and regulatory environment is excellent. The BDC team has been responsive and very supportive of our needs allowing us to develop a very productive relationship with the team and we plan to continue to use their well-tuned services and products."*
>
> **— Testing Services, Test Equipment, Silicone Vessels**

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CAPABILITIES



TESTING SERVICES

Comprehensive ISO/IEC 17025:2017 Accredited testing services for regulatory submissions or R&D on a vast array of medical device technologies



TESTING EQUIPMENT

Cardiovascular, structural heart and endovascular test systems with superior control and adaptability for durability, fatigue and bench testing applications



SILICONE VESSELS

Certified silicone mock vessels for durability testing and silicone models for simulation and R&D activities in all geometries, as well as patient-based datasets



SIMULATION SOLUTIONS

Standard or custom turnkey simulation systems that include clinically relevant vascular pathways and hemodynamics for device development and physician training



CARDIOMED

Regulatory, clinical, pre-clinical and quality system consulting for Class II and Class III medical devices through the complete product life cycle

To learn more about BDC's full range of capabilities and equipment, visit **BDCLabs.com** or call **303.456.4665**

Questions?

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www.bdclabs.com

info@bdclabs.com

303.456.4665

4060 Youngfield St.
Wheat Ridge, CO 80033

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