

**Cogmedix**

70 Hartwell Street  
W. Boylston, MA 01583  
Phone: 508-753-7473  
Fax: 508-799-0265  
Email: [info@cogmedix.net](mailto:info@cogmedix.net)  
Web: [www.cogmedix.net](http://www.cogmedix.net)



**WHO WE ARE**

**Cogmedix** is the Medical Device Contract Manufacturing division of Coghlin Companies Inc., a privately held manufacturing, engineering and worldwide fulfillment organization spanning four generations.

**Cogmedix** is an FDA compliant company operating in accordance with 21 CFR Part 820 of the regulatory standards.

**Cogmedix** is certified to ISO 13485:2003 by TÜV, SÜD America.

**Cogmedix** manufactures Class I and Class II medical, clinical and pharmaceutical devices for a variety of medical innovation companies.

**TOTAL TURNKEY MANUFACTURING**

**Cogmedix** is an ideal solution for companies seeking a partner with:

- Class I and Class II device manufacturing experience
- Strict compliance to 21CFR Part 820 of the FDA Code of Regulations
- Intellectual property protection and strict confidentiality
- In-house high speed printed circuit board assembly lines
- Global buying leverage for plastics, precision machined parts, sheet metal, electronics, cables, harnesses and LCD's
- Rigid DHR, DMR, serialization and traceability processes
- Product ramp experience with a focus on 50 – 10,000 units per year



**PRIMARY MARKETS SERVED**

- Critical Care
- Laboratory Devices
- Therapy and Rehabilitation
- Home Healthcare
- Aesthetic and Light-Based Devices
- Pharmaceutical and Diagnostic Products

**WHY CHOOSE COGMEDIX?**

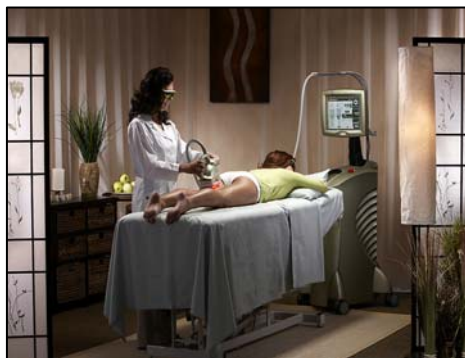
- World class quality system
- Global supply chain leverage
- Privately held and financially solid
- Reliable, responsive, flexible and referable
- Ownership commitment to customer satisfaction

**CORE CAPABILITIES**

- Documentation procedure refinement
- Prototyping and pilot builds
- Manufacturing process validation
- Scaled device manufacturing
- Clean room assembly
- Product serialization and traceability
- Product packaging and crating



**FEATURED PRODUCTS**





America

# CERTIFICATE

The Certification Body of  
TÜV SÜD AMERICA INC.

hereby certifies that

**Cogmedix. Inc.**  
70 Hartwell Street  
West Boylston, MA 01583 USA

has implemented a Quality Management System  
in accordance with:

**ISO 13485:2003**

The scope of this Quality Management System includes:

**Contract manufacturing of assemblies and  
finished devices for the electro/mechanical-medical  
device industry**

Certificate Expiry Date: June 5, 2011

Certificate Registration No: S 951 08 4770

Effective Date: January 30, 2009



  
\_\_\_\_\_  
Gary W. Minks  
VP, Regulatory Affairs

