Job Title: Mechanical Engineer

Reports to: VP of Engineering

Scope of Supervision: None

EDUCATION, BUSINESS EXPERIENCE AND PHYSICAL REQUIREMENTS

- Bachelor’s degree in Mechanical Engineering or similar technical discipline and a minimum of 3 years relevant work experience.
- Working CAD expertise; including AutoCAD and SolidWorks experience.
- Experience in pneumatics/hydraulics, pumps, valves, filters, plumbing and similar mechanical systems.
- Strong analytical and organizational skills and demonstrated problem-solving abilities.
- Knowledgeable in molded plastic part design and the molding process as well as metal part fabrication.
- Familiarity with assembly processes, DFM and the corresponding documentation.
- Interact and assist with Quality in internal investigation of NCR’s, CAPAs, and Customer complaints.
- Able to lift 50 pounds
- While performing the duties of this job, you will be regularly required to be independently mobile
- Other duties as assigned by Management.

REQUIRED COMPETENCIES

Desired:
- Understanding and experience with Class II or higher medical device requirements (FDA, MDD, CE Mark, ISO 13485, etc.) and safety agency requirements (UL, Intertek, etc.).
- Develop product cost estimates, project costs and time estimates.
- Previous working experience with patent attorneys and supporting IP portfolios.
- Working knowledge of EPICOR MRP / ERP system.
- Working knowledge of documentation control and configuration management.
- Experience with centralized document management systems and ability to propose such a system.

DESCRIPTION OF RESPONSIBILITIES

This engineering team member is responsible for cradle to grave designing, documenting, prototyping, testing and commercializing new medical products using company policies and procedures. The Engineer is also responsible for creating, releasing and maintaining device documentation (part CAD files, device Design History Files (DHF), test records, etc.) that are compliant with industry guidelines, regulatory standards and company requirements. Other duties in support of product development include interfacing with internal Tactile Medical groups such as Manufacturing Operations, Quality/Regulatory, Supply Chain, Clinical and Marketing as well as outside organizations such as suppliers, test facilities and regulatory bodies.

KEY RESULT AREAS:
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<tr>
<th>Job Title:</th>
<th>Mechanical Engineer</th>
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<tr>
<td>Reports to:</td>
<td>VP of Engineering</td>
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- Apply engineering knowledge and skills to design and develop medical products on time and within budget.
- Document medical device designs using CAD and MS Suite software to define product requirements.
- Maintain documentation necessary for a DHF, including Design Input, Design Verification Plans/Reports, Design Validation Plans/Reports, Test Protocols/Reports, and Design Output.
- Create ECOs to release & maintain component & product specifications, BOMs and DHFs.
- Write specifications, test protocols, and reports to document and demonstrate proper device functionality.
- Procure parts and oversee outside supplier efforts in the fabrication of functional prototypes.
- Work with outsourcing partners to coordinate pilot production of new products.
- Complete product verification and validation testing and the associated test reports.
- Implement product improvements to address customer complaints, cost of goods, and/or reliability issues.
- Contribute to the intellectual property position of the company via invention and patent applications.

**ACKNOWLEDGMENT**

I understand and agree to comply with this job description:

Employee's Printed Name: _______________________________________________________________

Employee's Signature: ___________________________ Date: ________________

This Job Description was last created on: (4/27/2017)