Position: Quality Engineer
Reports to: Quality Manager

Position Summary
The Quality Engineer is responsible for maintaining and improving the quality of Tactile Medical products and processes and improving supplier management and performance.

Accountabilities & Responsibilities
- Coordinates the tasks for the electronic Quality Management System (QMS)
- Plans and conducts the analysis, inspection, design, tests, and/or integration of test methods to assure the quality of assigned products or components
- Develops test methods and participates in the assessment of incoming, in-process and final test/inspection.
- Performs root cause investigations and develops corrective action plans for product and process non-conformities.
- Coordinates the documentation review, inspection workflow, training, problem solving and calibration for Tactile Medical products and test equipment
- Tracks and reports quality metrics
- Advises on changes and their implementation and provides training, tools, and techniques to enable others to achieve quality
- Utilizes statistical analysis techniques to determine product acceptance and AQL sampling plans, evaluate process capabilities, and develop statistically sound tolerance limits
- Participates in the non-conformance reporting system, driving timely disposition and closure. Leads and/or participates in MRB meetings. Identify non-conformance trends and develop and administer technical investigation and corrective action plans to resolve recurring quality problems
- Contributes to the development and implementation of product test plans including verification and validation of products and processes
- Serves as liaison to design, procurement and manufacturing engineering
- Participates as a resource in validations applicable to processes and products
- Performs standard quality engineering reviews of design documentation for compliance with stated requirements, including supplier quality and company quality records
- Works with Manufacturing, Supply Chain, and Engineering as needed to address supplier quality issues
- Monitors and communicates supplier performance on an ongoing basis in order to develop improvement plans
- Maintains appropriate supplier evaluation files and records
- Coordinates and performs supplier audits as needed
- Manages supplier corrective action requests to ensure timely completion and effective
- Willingness and ability to travel up to 15%
Education & Experience:
- Minimum of 3 years of experience as a Quality Engineer in the medical device industry
- BA/BS degree in science or other technical field

Knowledge & Skills:
- Medical Device Quality System Knowledge Including 21 CFR Part 820 (QSR) & ISO 13485
- Demonstrated skills in statistical analysis
- Strong computer skills
- Experience with CAPA required
- Certified Quality Engineer (CQE) and/or Certified Quality Auditor (CQA) preferred

Competencies:
- Strong written and oral communication skills
- Ability to review, analyze, summarize, and interpret data; draw conclusions and make appropriate recommendations and decisions; write reports; and lead or conduct teams and meetings

Influencing

It is the policy of Tactile Medical to provide equal opportunity (EEO) to all persons regardless of age, color, national origin, citizenship status, physical or mental disability, race religion, creed, gender, sex, sexual orientation, gender identity and/or expression, genetic information, marital status, status with regard to public assistance, veteran status, or any other characteristic protected by federal, state or local law. In addition, Tactile Medical will provide reasonable accommodations for qualified individuals with disabilities.

ACKNOWLEDGMENT
I have received, reviewed and fully understand the job description for this position. I further understand that I am responsible for the satisfactory execution of the essential functions described above.

Employee’s Printed Name: _________________________________________________________________

Employee’s Signature: _________________________________ Date: __________________