Description	
Job Title	Quality Engineer
Reports to Title	Quality Assurance / Regulatory Affairs (QARA) Manager
General Accountability	Key player in setting up compliant manufacturing environment where electro medical devices will be assembled and stored. Requires strong understanding of the manufacturing life cycle and ability to work closely with the Head of Operations. Responsible for conducting production inspections and final product release.
Duties and Responsibilities	1. Support projects related to manufacturing plant layout/process to ensure efficient and timely completion. 2. Manage multiple projects in various stages of production, including manufacturability assessment, process improvements, quality inspections, and quarantine and inventory control. 3. Assist with design transfer to manufacturing, including quality control activities from production processes to shipment of the final product. 4. Work with Contract Manufacturer (CM) to implement new manufacturing processes. 5. Arrange shipping and logistics for product quality assurance related testing activities. Keep track of testing samples received from potential suppliers and ensure effective communication regarding closure of such activities. 6. Analyze manufacturing reports provided by CM. 7. Inspect product including labeling and documentation for release of finished goods. 8. Manage product traceability and labeling. 9. Manage and maintain product device history records. 10. Ensure that all production employees are familiar with, trained on, and follow all manufacturing procedures related to their jobs Ensure that changes to procedures are reviewed, approved and validated prior to implementation. 11. Oversee creation and review of documentation for nonconforming product. 12. Participate in product investigations related to customer complaints and corrective actions. Use FMEA methodology to expose issues during investigation of product related failures 13. Works with Engineering department ensuring that engineering change orders affecting production related changes are reviewed 14. Keep management abreast of significant issues identified during production related quality activities as well as actions being taken to improve correct the situation. 15. Assist with revisions and updates to quality procedures, standardized work instructions 16. Identify and lead process validation activities. 17. Maintain equipment calibration program to ensure equipment is calibrated in a timely manner.

	18. Participate in supplier management activities. Identify supplier quality issues and report to management in timely manner. 19. Participate in risk management meetings and related activities such as verification of risk mitigation implementation in products and processes. 20. Responsible for completion of an annual share of Internal Quality Audits. 21. Participate in 3rd party audit and inspection activities (ISO, Notified Body, FDA, Health Canada, etc.). 22. Stay up-to-date and follow procedures related to the job. 23. Other duties as assigned.

Competencies	
Education	Bachelor degree in Engineering discipline or equivalent
Certifications	
Key Attributes (experience, skills and technical knowledge)	• Preferably 5 years' experience in medical device manufacturing environment, with experience in electronic and mechanical assemblies • Knowledge of Lean manufacturing practices • Knowledge of testing, Quality Control and Quality Assurance processes of electromechanical components and product assemblies • Self-driven individual with excellent work ethic and a can-do attitude • Active learner with the ability to thrive in a fast-paced, results-oriented, start-up environment • True team player with strong interpersonal skills and commitment to the team's success. • Creative problem solver with exceptional verbal and written communication skills. • Excellent time management skills with keen attention to detail and ability to multi-task. • Able to travel occasionally

Employee Job Description Acknowledgement

I have read this job description and I completely understand all my job duties and responsibilities. I am able to perform the essential functions as outlined with or without reasonable accommodation. I understand that my job may change on a temporary or regular basis according to the needs of Profound Medical Inc. without it being specifically included in

the job description. If I have any questions about job duties not specified on this description that I am asked to perform, I should discuss them with my immediate supervisor.

Employee Signature: _____

Date:_____

Employee's Name (please print):

Functional VP Signature :_____

Date: _____

Name (please print):