

Management System Policy

Document Owner: CEO

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Saluda is a start-up company designing and developing a ground-breaking new competitive implantable spinal cord stimulation (SCS) device incorporating closed loop feedback that is approved for sale in the US and Europe. Saluda employees and management are committed to exceeding our customers' expectations by achieving innovation through design and technology to create unsurpassed product quality, reliability, and patient safety through effective, efficient and compliant processes.

We are committed to providing and fostering a company culture that delivers consistent quality products and services. Our success relies on communication, co-operation and involvement at all levels. We will achieve this by creating a culture which recognises that quality is inherent in all aspects of our activities encompassing the concept, design, development and commercialisation of our products. Through the implementation and improvement of this policy and our processes flowing through every phase of our operations our success is a result of the performance of every person in our organisation.

We enhance our system by creating an annual Management System Plan whereby we define our objectives, targets and measures that are regularly analyzed and reviewed. Outcomes are communicated and identified improvements incorporated to ensure our system will continuously improve. We will perform regular compliance reviews to ensure that we comply with applicable regulatory requirements, resulting in consistent delivery of product, process, service and relationship excellence to customers. In accomplishing this we will maintain our Management System by managing our risk by committing to and achieving objectives in our Management System Plan including those related to:

- Product development and improvement.
- Elimination of work related injury and illness
- Management system planning and improvement.
- Supplier quality assurance.
- Personnel training and competence.
- Regulatory compliance and internal/external audits.
- Process effectiveness and efficiency.
- Communicating performance measures to employees and stakeholders
- Preventing pollution directly and through influence

The Management of Saluda will regularly review the performance of this policy to ensure its continued suitability to the needs of Saluda and our customers.

This policy is available to interested parties on the Saluda Medical website and by request direct to the company.



Signed

15/08/2014
Date

Dr John Parker
Chief Executive Officer
Saluda Medical Pty Ltd