



# Title: Quality Policy

Reference No: DR 28

Version No: 03



<b>Current Version:</b>	Version 3	<b>Live:</b>	February 2024
<b>Owner:</b>	Mark Sacofsky	<b>Date for Review:</b>	February 2025
<b>Previous Version:</b>	Version 2	<b>Live:</b>	August 2021
<b>Owner:</b>	Samuel Zalcborg		

Farla Medical Healthcare Limited's Senior Management is committed to delivering safe and effective, high quality products that meet the demands of clinicians in delivering optimal patient care, through a comprehensive understanding of developing technologies, changing medical practice and the regulatory environment.

Quality Policy is applicable to the organisation and is reviewed for continued suitability, Farla Medical Healthcare Limited is committed to:

- Provide a reliable and efficient supply of a comprehensive range of products to its Customers, whilst conforming to the Company's objectives and statutory, regulatory and safety regulations and to the requirements of EN ISO 13485:2016 and MDD 93/42/EEC Annex V (As amended by Directive 2007/47/EC), LSAS, customer and other specific regulatory requirements which include looking at risks and opportunities for improvements within the UK facility.
- Maintain a management system that meets the requirements of ISO 13485:2016 and includes quality system objectives that are regularly reviewed by the management team.
- Drive continuous improvement by the setting, monitoring and reviewing of quality performance indicators with feedback derived from our customers, internal audits, CAPA and other measures; Use the principles of ISO 14971 to mitigate risk to acceptable levels wherever identified.
- Provide resources to maintain and improve the effectiveness of the quality management system in order to meet the requirements of its Customers and to enhance Customer Satisfaction.
- Establish Quality and functional level of the business that are appropriate to the functional area, are Objectives at each relevant measurable, will support the Quality Policy and will facilitate the Company's aim to provide a service to its Customers.
- Facilitate communication throughout the Company, monitor Customer satisfaction and to continuously monitor the effectiveness of its Quality Management System and the Quality Policy in order to improve its suitability and effectiveness.

Establish a documented Quality System that will allow the Company to fulfil its contractual obligations by:

- Ensure that all activities that directly affect the quality of the service are carried out under controlled conditions.
- The continuous monitoring and analysis of quality indicators that provide data to enable continual improvement against the Customer's needs and expectations.
- Providing resources, up to date instructions and training to all personnel, together with the promotion of quality awareness.

**Role: Director**

DocuSigned by:  
  
8C1BF7EECDD84ED...

**Name: Mark Sacofsky**

16-Feb-24 | 5:48:53 PM GMT

**Date:** \_\_\_\_\_