

## Quality Policy Statement

*(Taken from Section 5.3 of the Planer Quality Manual)*

As manufacturers and suppliers of Controlled Rate Freezers & Accessories, Bench top Incubators and Alarm & Monitoring Systems, Planer PLC are committed to the design, manufacture and supply of safe, effective and consistent products for use by the Scientific and Medical industries by:

- meeting or exceeding customer expectations
- satisfying the requirements of the Quality Management System
- measuring and improving operational performance
- complying with regulatory and statutory requirements
- continually reviewing for suitability

The QMS of Planer PLC, as documented in this manual and associated documents, complies with the requirements of ISO13485:2016, Medical Directive 93/42/EEC:1993 as amended by 2007/47/EC, FDA 21 CFR Part 820 & CMDR.

This manual describes the activities employed by the organisation in order to satisfy the requirements of ISO13485:2016, Medical Directive 93/42/EEC:1993 as amended by 2007/47/EC, FDA 21 CFR Part 820 and CMDR and indicates the lines of inter-relationship and responsibilities within the organisation. The policy also ensures all employees are fully aware of the requirements of the QMS and are appropriately trained to ensure its continued effectiveness.

In order to ensure that the organization demonstrates a commitment to comply with the requirements and to maintain the effectiveness of the system, this policy and associated objectives are continually monitored and evaluated for suitability and effectiveness. This is achieved by means of internal auditing and management review in order to establish opportunities for improvement and to ensure their implementation and validation by the continual monitoring of performance and trends.



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