P3 Medical Limited
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Quality Policy

P3 aims to be a strong, reliable and financially successful medical device company. Products will be designed and manufactured as well as distributed on behalf of other manufacturers.

Quality is seen as an integral part of the business management process and as such cannot be segregated, isolated or allocated to an individual or department. Therefore the quality of the organisation's products and services is the responsibility of all employees within the organisation.

It is therefore important that all individuals understand their role, interactions with others and the contribution they make in maintaining and where appropriate continually improving the quality of the products and services supplied by the organisation.

The organisation is committed to maintaining certification to:

- EN ISO 9001:2015 Quality Management Systems
- EN ISO 13485:2016 Medical Devices Quality Management System
- 93/42/EEC European Medical Device Directive including 2007/47/EC
- EU 2017/745 Medical Device Regulations (transitioning to)
- 21 CFR 820 USA GMP

The organisation is committed to responding to the needs of:

- The Patient (who ultimately uses our products)
- The User
- The Customer
- Our workforce
- Our Suppliers
- Laws, regulations and statutory requirements
- Product Standards

It is the intent of the company to cause zero harm to the patient or user.

The organisation will establish and monitor objectives to ensure that the organisation achieves the requirements of this policy through the application of the Business Management System. The objectives will be measurable and set at corporate, project, departmental and individual levels, as required, to achieve the requirements of the organisation and its customers.

DocuSigned by:
Simon Talbot
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Simon Talbot
06th July 2018