



## Company quality policy

The company is committed to the achievement of quality throughout its organisation. The company's quality system is documented so that staff have the means to ensure that all products conform to specified requirements.

The objective for quality is to maintain the documented quality system to the current requirements of standards BS EN ISO 13485:2016, EU Regulation 2016/425 Module D, EU MDR 2017/745, UK MDR 2002 to ensure that all actions called for therein are implemented and maintained.

The design, production and sale of all products are always controlled, so that the highest standard of quality can be passed on to customers. This realises customers' needs and expectations and forms a major part of the company's objectives. This is carried out at their facility in Harlow, Essex. UK.

The company's policy is actioned by: -

- Employment of resources necessary to continuously apply the quality policy.
- Use of written management procedures and encouragement to staff to continuously recognise and apply their responsibilities as referenced in the QA Manual.
- Regular measurement and review of the quality policy, using up-to-date data.
- Retention of quality records, drawings technical files for the lifetime of the device plus a minimum of ten years to facilitate traceability and audits.
- Understanding external issues affecting the design or production of company products.
- Early detection of non-conformances and the rapid application of corrective and preventative actions.
- Close liaison with suppliers and customers.
- Maintenance of suitable premises and working environments as required by the Health and Safety Executive.
- Employment of staff with direct responsibilities for quality assurance and quality control.

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Title: Managing Director

Signature:

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