

Flexicare 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, Flexicare offers innovative solutions based on a foundation of Total Quality, Total Care.

In support of this policy Flexicare will:

- Work in partnership with its employees in maintaining and improving their quality system
- Ensure that all activities are adequately resourced and carried out by trained and competent personnel
- 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
- Maintain robust systems to ensure continued compliance with ISO13485, FDA Quality System Requirements, Medical Device Directive (93/42/EEC), and other relevant statutory and regulatory requirements
- Use the principles of ISO 14971 to mitigate risk to acceptable levels wherever identified.
- Establish partnerships with suppliers and interested parties to provide an improved service

Flexicare will establish quality objectives which will support this policy and will monitor the effectiveness of these objectives as part of the management review process.

The overall effectiveness of the quality system will be judged by meeting our customer requirements, regulatory compliance and by achieving business objectives.



Managing Director

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