



Quality Policy

Flexicare is committed to delivering safe, effective and 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.

Flexicare's Quality Policy is an integral part of the company's Quality Management System and the Board of Directors shall ensure that all employees follow requirements as detailed in the Quality Management system.

In support of this policy Flexicare will:

Flexicare Medical Limited

Maintain robust systems:

- To ensure continued compliance with BS EN ISO 9001, ISO 13485, Med Dev 93/42/EEC, MDR (EU) 2017/745, UKCA, MDSAP (Australia, Canada, Brazil, Japan and the USA), CFR 820, LSAS, customer and other specific regulatory requirements which include looking at risks and opportunities for improvements
- 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;
- 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; and
- Establish quality objectives which will support this policy and will monitor the effectiveness of these objectives as part of the management review process.

Flexicare GmbH, Flexicare Srl and Flexicare B.V

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- 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 Flexicare's business objectives.

Managing Director

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Flexicare (Group) Limited

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