Q provision
Quality Solutions

ISO 13485
MEDICAL DEVICES

Requirements for regulatory purposes:

- This standard specifies requirements for a quality management system that can be used by an organisation for the design and development, production, installation and servicing of medical devices, and the design, development of related services.
- It can also be used by internal and external parties, including certification bodies, to assess the organisation's ability to meet customer and regulatory requirements.
- These requirements are complimentary to technical requirements for products.

There is a regulatory requirement to operate a quality management system in order to apply a CE Mark to medical devices.

CALL **0191 372 2117**

- ISO 9001
- Machinery Directive
- ISO 13485
- Medical Device Directive
- Technical File Compilation

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