

Title: **ISO9001 to ISO13485 Statement**

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Department: Quality / Regulatory

Graphic Controls Ltd has made the decision to upgrade its Quality Management System [QMS] from ISO9001 to ISO13485.

What is ISO13485?

"ISO 13485 is an International Organization for Standardization (ISO) standard, published in 2016, that represents the requirements for a comprehensive quality management system for the design and manufacture of medical devices."

Why has Graphic Controls moved to ISO13485?

"Graphic Controls Ltd supplies into both Industrial and Medical sectors and the tighter controls on documentation, inspection and traceability of ISO13485 made it an ideal standard to improve our business systems"

How does it affect me the customer?

"In terms of Service and Quality of product it will only help enable us to maintain and improve our existing products. It is still an ISO Standard and is certified by a 3rd Party Certified Notified Body"

What are the benefits for me the customer?

"Key areas of ISO13485:

- **Product Specifics:** Risk Management / Evaluations / Advisory Notes / Cleanliness / Recall / Monitoring & Measurement / Statistical Controls / Concessions & Deviations.
- **Regulatory:** Harmonisation of quality management system regulations around the world. Meeting product regulation requirements is a key element helping develop safe products which have an effective performance.
- **Documentation:** Documented procedures for: Product Files / Retention / Maintenance / Health & Cleanliness / Responsibilities / Purchasing / Installation & Service / Validation / Identification / Traceability & Training / Process Control / Data Analysis / Recalls / Advisory Notes.
- **Customer Satisfaction:** In the regulatory environment of medical devices customer satisfaction is felt to be too subjective. The requirement is to monitor all data / information to demonstrate customer requirements have been met."

Graphic Controls Ltd is always looking to improve its products and processes while maintaining its focus on customer satisfaction. ISO13485 is a more comprehensive standard than ISO9001 which we feel will benefit all parties.



Simon Davies

Quality Manager

Dated: 06/09/2016