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"We Engineer the Quality of Your Success"

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MEDICAL DEVICE MANUFACTURER

CLIENT's SITUATION

A medical device manufacture was awarded a \$2 million/year contract to supply their new product into Europe. However, they had to get registered to **EN 46001** (ISO 9001 and additional medical device requirements) and meet all the requirements of the Medical Device Directive (**MDD**) within 6 months.

PQA's TASK

PQA was called to help implement the **EN 46001** quality system and incorporate the additional requirements to meet the **MDD**.

PQA's ACTION

PQA assisted the company in preparing and implementing the quality system. During the project, to allow sales to Canada and the U.S. as well, the scope was expanded to include the requirements of the U.S. FDA Good Manufacturing Practices and the **ISO 13485** Quality System Standard for Medical Devices.

CLIENT's RESULT

Six months after starting implementation, the company was registered to **EN 46001** and granted the right to label their products with the **CE** mark, permitting access to the European Economic Community. The company has met all the requirements for the FDA Good Manufacturing Practices and the Canadian Health Protection Branch.