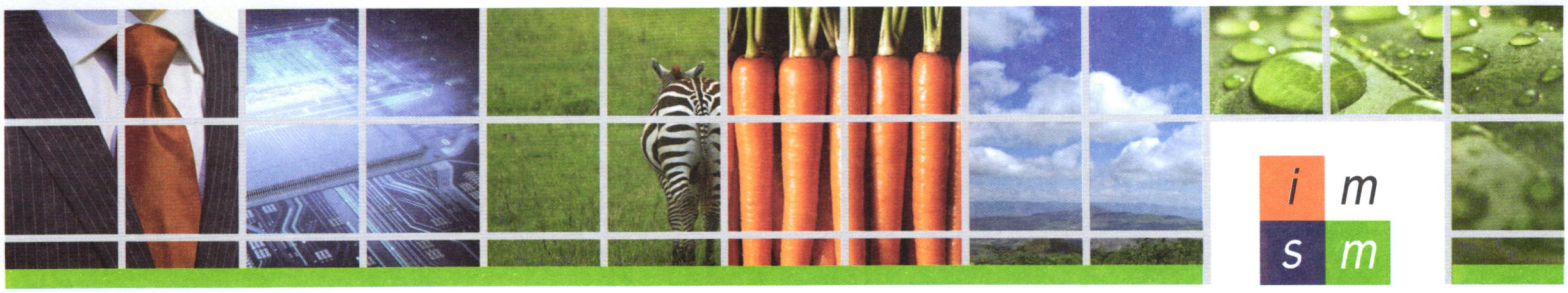

iso specialists

International Tube

690 Enterprise Drive, Royersford, Pennsylvania 19468, USA

Our Ref: UCO1073

Date: 29th August 2016

To whom it may concern

IMSM Limited has assisted the above organisation in the preparation, documentation and implementation of a quality management system to address the requirements of ISO 13485:2003, with the permissible exclusion of:

ISO Clause 7.5.1.2.2 Installation activities
ISO Clause 7.5.1.2.3 Servicing activities
ISO Clause 7.5.1.3 Particular requirements for sterile medical devices
ISO Clause 7.5.2.2 Particular requirements for sterile medical devices
ISO Clause 7.5.3.2.2 Particular requirements for active implantable medical devices and implantable material

In the opinion of IMSM Limited, the organisation is now qualified to apply for third party certification, if required, with the confidence of knowing that they have a management system capable of meeting the requirements of the aforementioned standard.

Yours sincerely

Mike Green
Technical Manager
IMSM Ltd

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