



International Tube

690 Enterprise Drive, Royersford, Pennsylvania 19468, USA

Our Ref: UCO1073

Date: 29th August 2014

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 7.5.3.2.2 Particular Requirements for Active Implantable Devices

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

Nadine Bryars
Assessor Logistics Manager
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