



AdDent, Inc.
43 Miry Brook Road, Danbury, Connecticut 06810, USA

Our Ref: UCO1139

Date: 28th September 2017

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:

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|----------------------|---|
| ISO Clause 7.5.1.2 | Control of production and service provision – specific requirements. |
| 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 medical 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

Mike Green
Technical Manager
IMSM Ltd

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