



Accellent Inc
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October 27, 2011

Dear Valued Customer;

Accellent's Quality Management System (QMS), is focused on meeting or exceeding customer requirements and continual improvement. The QMS supports our business objective of providing services to the medical device industry that result in "safe and effective" components and finished devices. The Accellent Quality Management System is designed to satisfy International Standards ISO 9001:2008, ISO 13485:2003, and EN ISO13485:2003/AC:2009, and is compliant to U.S. Food & Drug Administration (FDA) 21 CFR Part 820 – Quality System Regulation. For specific customer needs, our quality management systems can be supplemented to meet other regulatory requirements (CMDR, MDD).

All of the Accellent Facilities have been certified to either, or both ISO 13485:2003 and EN ISO13485:2003/AC:2009 by TUV SUD America, Inc. and TUV SUD Product Service GmbH, respectively. Some facilities also possess additional quality system certifications, based upon business needs. Copies of the current certificates for each Accellent location can be found on the Accellent website (WWW.Accellent.com) under the "Why Accellent" Tab.

If you need additional information or have any questions, please feel free to contact me.

Sincerely,

A handwritten signature in black ink that reads "Denyse Collins".

Denyse Collins
Sr. Director Quality Management and Regulatory Affairs

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978-570-6856

DC/dja
attachments