

GRANITE. QUALITY.



Granite Receives ISO 13485:2003 Certification

Granite Microsystems, Inc. an, ISO 9001:2000 certified company, announced that it has earned the ISO 13485:2003 certification – a globally-recognized standard of quality management for medical device manufacturers. The company has successfully completed its ISO 13485:2003 certification audit and has been awarded a final certificate, and believes that achieving this certification gives it a unique competitive edge to improve time-to-market for new products while continuing to maintain the highest quality for all products it designs and manufactures for global OEMs in the medical marketplace.

Matt Bauza, Granite's Quality Manager, stated: "We are quite pleased that we were awarded the certified status on our first attempt." He continued, "This is a testament to the efforts that Granite put forth over the years to stress quality first in everything we do."

"This further substantiates that Granite's commitment to quality will continue to play a leading role in our ongoing growth" said Dan Armbrust, CEO of Granite. "We have several mature proprietary tools, including our P.A.C.E.⁽¹⁾ and N.A.B.S.⁽²⁾ systems" he continued, "that help us realize quality levels that would not be possible without these controls. Achieving the ISO 13485 certification has served to further validate the success of our processes and systems."

Granite's facilities were audited and certified by Lloyd's Register Quality Assurance (LRQA), a global registry firm recognized for excellence in providing accredited assessment and certification to multiple standards, including the ISO 13485:2003 standard.

As a global company, Granite is also moving toward independent ISO 13485 certification for its facility in Shanghai, China. This high-mix, low-volume facility is built on the same high standards as the company's state of the art North American facility and is currently ISO 9001:2000 certified. "We anticipate a very smooth certification audit and approval process at our Asia facility," said Bauza, "since that facility utilizes the same world class automation, tools and processes as our North American facility."

About the ISO 13485 Standard

ISO 13485, published in 2003, is an important quality management standard and represents the requirements for a comprehensive management system for the design and manufacture of medical devices. The standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services. Further, ISO 13485 is harmonized with the U.S. FDA's good manufacturing practices. Granite has pursued this certification as part of an ongoing commitment to achieve compliance with regulatory requirements based on the needs of the medical community at a global level.



ISO 9001:2000
Certified

About Granite Microsystems, Inc.

Granite Microsystems is an Applied Computing Solutions Provider providing turnkey computing systems and sub-systems to OEMs serving the medical and embedded computing markets. As an Applied Computing Solutions Provider, Granite's mission is to operate as a virtual division of an OEM and provide perfect fit computing solutions that meet their specific engineering and manufacturing needs. Our value proposition focuses on lowering the OEM's Total Cost of Ownership by positioning Granite as a direct extension of the OEM's engineering, manufacturing, quality, procurement, and service programs – a business model where Granite provides complete end-to-end services over the entire product life cycle. This approach allows the Granite OEM partner to re-deploy resources on higher value activities and create significant benefits including increased ROI and improved market share.

- (1) P.A.C.E. is an acronym for "Process Automation for Copy Exact", a robust fourth-generation manufacturing automation tool that allows Granite to achieve unparalleled consistency.
- (2) N.A.B.S. is an acronym for "Networked, Automated Burn-in System", Granite's proprietary tools for hardware assessment and automated stress testing for assurance of quality at a component and system level.



"An Applied Computing Solutions Provider"

Granite Microsystems, Inc. • 800.822.2983 • www.granitemicrosystems.com



CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

**Granite Microsystems, Inc.
10202 North Enterprise Drive
Mequon, Wisconsin 53092, USA**

has been approved by Lloyd's Register Quality Assurance
to the following Quality Management System Standards:

ISO 13485:2003

The Quality Management System is applicable to:

**Design, Manufacture and Servicing of Computers,
Peripheral Equipment and Computing Solutions
for use in the Medical Device Industry.**

Approval
Certificate No: UQA 0111116/B

Original Approval: March 18, 2009

Current Certificate: March 18, 2009

Certificate Expiry: February 28, 2011

Cheryl Distefano

Issued by: Lloyd's Register Quality Assurance, Inc.



001

This document is subject to the provision on the reverse
1401 Enclave Parkway, Suite 200, Houston, Texas 77077, USA

This approval is carried out in accordance with the LRQA assessment and certification procedures and monitored by LRQA.
The use of the UKAS Accreditation Mark indicates Accreditation in respect of those activities covered by the Accreditation Certificate Number 001

Macro Revision 13



CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

**Granite Microsystems, Inc.
Mequon, Wisconsin, USA**

has been approved by Lloyd's Register Quality Assurance
to the following Quality Management System Standards:

**ISO 9001:2000
ANSI/ISO/ASQ Q9001-2000**

The Quality Management System is applicable to:

**Design and Manufacture of Commercial and
Industrial Computers and Peripheral Equipment**

Approval
Certificate No: UQA 0111116

Original Approval: February 25, 1999

Current Certificate: February 28, 2008

Certificate Expiry: February 28, 2011

Issued by: LRQA, Inc. Houston



This document is subject to the provision on the reverse
1401 Enclave Parkway, Suite 200, Houston, Texas 77077, USA

This approval is carried out in accordance with the LRQA assessment and certification procedures and monitored by LRQA.

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