



**\*\*\*\*\*SPECIAL ANNOUNCEMENT\*\*\*\*\***

**ISO/TS16949:2002 & ISO13485:2003 Certification Recommendation**

PTI Engineered Plastics, Inc. is pleased to announce that our organization has successfully completed our certification audits to the following standards:

- ISO9001:2000 Quality Management Systems
- TS/ISO16949:2002 Quality Management Systems for Automotive
- ISO13485:2003 Quality Management Systems for Medical Devices

Our registrar, BSI Management Systems conducted a thorough four (4) day audit on each standard, and has, with confidence recommended PTI for registration to the accrediting body.

Included as part of the certification audit was the approval of our Controlled Environment processes (Manufacturing and Secondary) to ISO14644 (1-8), Clean Rooms and Controlled Environments. These areas were qualified as a subset to the ISO13485:2003 standard. In addition, PTI Engineered Plastics, Inc. quality management system was reviewed to the requirements of FDA 21CFR Part 820 and found to be compliant.

The recommendation and final RAB approval will take approximately 30-45 days. Certificates of Approval will be received for each standard after the final approval has been achieved. These certificates will be posted on the PTI Engineered Plastics website, [www.teampti.com](http://www.teampti.com).

Should you require further information regarding the entire scope of certification and/or additional information regarding our capabilities to support your Quality needs, please feel free to contact Nancy Gusmano, Director of Quality, PTI Engineered Plastics, Inc. @ [ngusmano@teampti.com](mailto:ngusmano@teampti.com) or 586-263-5100 E.2239

For more information regarding the specific standards, please feel free to click on the links identified below:

**Automotive:** [www.bsiamericas.com/Automotive/ISOTS16949/index.xalter](http://www.bsiamericas.com/Automotive/ISOTS16949/index.xalter)

**Medical Devices:** [www.bsiamericas.com/MedicalDevices/QualityManagement/index.xalter](http://www.bsiamericas.com/MedicalDevices/QualityManagement/index.xalter)

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