

Evonik subsidiary certified as a supplier to medical device manufacturers

September 7, 2011

Evonik Industries subsidiary APT Europe GmbH has been successfully certified according to EN ISO 13485:2003. This international standard specifies requirements for the quality management systems of medical device manufacturers and their suppliers. Compared to ISO 9001, ISO 13485 places particular emphasis on ensuring consistent product quality and controlling and verifying all relevant processes, as well as documentation and traceability.

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Manufacturers of medical devices must ensure that their suppliers comply with the requirements of EN ISO 13485. This certification simplifies the mandatory supplier qualification process for VESTAKEEP® customers. Besides ensuring consistent product quality, Evonik is also making a significant contribution to reducing customer expenditures for medical device registration. The product portfolio of Evonik includes stock shapes made of VESTAKEEP® PEEK medical grades for the manufacturing of biocompatible and biostable products.

Dr. Herbert Groothues, Regulatory Affairs VESTAKEEP®: “We believe that our decision to become ISO 13485 certified is a proactive one that not only anticipates the demands of our customers but also demonstrates our commitment to providing quality services.”

VESTAKEEP® PEEK polymers are used in medical technology because of their excellent biocompatibility and biostability. Implants made of VESTAKEEP® PEEK are highly resistant to wear and have advantages to materials such as titanium in many areas. Applications include spinal and dental implants, orthopedic devices, and implants for oral and maxillofacial surgery.

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Image Caption:

Manufacturing of semi-finished PEEK products in a clean-room.

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Dr. Klaus Engel, Chairman
Dr. Wolfgang Colberg,
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Company information

Evonik is the creative industrial group from Germany. In our core business of specialty chemicals, we are a global leader. In addition, it has energy and residential real estate operations. Our performance is shaped by creativity, specialization, reliability and continuous self-renewal.

Evonik is active in over 100 countries around the world. In fiscal 2010 more than 34,000 employees generated sales of around €13.3 billion and an operating profit (EBIDA) of about €2.4 billion.

Disclaimer

In so far as forecasts or expectations are expressed in this press release or where our statements concern the future, these forecasts, expectations or statements may involve known or unknown risks and uncertainties. Actual results or developments may vary, depending on changes in the operating environment. Neither Evonik Industries AG nor its group companies assume an obligation to update the forecasts, expectations or statements contained in this release.

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