

Definiens AG Receives DIN EN ISO 9001:2008 and EN ISO 13485:2007 Certification

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Press release from: [Definiens AG](#)

Munich, Germany / Morristown, NJ – July 23, 2009 – Definiens, the number one Enterprise Image Intelligence® company, has successfully completed the certification process for the worldwide common quality management standards DIN EN ISO 9001:2008 and EN ISO 13485:2007. Definiens has demonstrated that its process workflow—from design and development to production, sales, installation and customer service—is fully compliant with the regulations defined by the International and European standardization authorities. The certification audit was conducted by the Notified Body Landesgewerbeamt Bayern, a TÜVRheinland® company.

“Aligning the company’s structure and processes to meet the requirements of DIN EN ISO 9001:2008 certification represents a significant milestone for Definiens,” said Dr. Wolfgang Rencken, Chief Operating Officer at Definiens. “Certification provides our customers with further assurance about the quality of our processes and products, as well as increasing the efficiency of our internal workflows. Both of which will help further Definiens’ market standing.”

Along with the general requirements for quality management systems set in DIN EN ISO 9001:2008, Definiens maintains the requirements of EN DIN 13485:2007. This standard defines the quality management system requirements for Medical Devices.

“The EN ISO 13485:2007 certification enables Definiens to design, develop, produce, sell and service Medical Devices under controlled conditions,” said Dr. Dirk Colditz, Director Quality Management and Safety Officer Medical Devices of Definiens. “This is the ultimate precondition to receiving CE-approval to enable marketing of the company’s Medical Imaging software products and IVD-products, which are currently under development.”

Definiens in Life Sciences

Definiens supports Life Sciences organizations by automating image analysis on an enterprise level, from drug discovery to diagnostics. Its image analysis software enables pharmaceutical and biomedical companies to interpret vast numbers of digital images accurately and consistently. Definiens applications improve the measurement of cell assays, the examination of tissue samples and the interpretation of non-invasive imaging, helping organizations to advance translational research and personalized medicine.

Definiens in Medical Imaging

By automating image analysis, Definiens supports healthcare providers in analyzing and interpreting vast numbers of digital images accurately and consistently. Definiens improves the analysis of tissue samples and non-invasive imaging, enabling translational medicine - from early diagnosis to personalized treatment.

About Definiens

Definiens is the number one Enterprise Image Intelligence® company for analyzing and interpreting images on every scale, from microscopic cell structures to satellite images. The Definiens Cognition Network Technology®, developed by Nobel Laureate Prof. Gerd Binnig and his team, is an advanced and robust context-based technology designed to fulfill the image analysis requirements of the Medical, Life Science, and Earth Science markets. The technology is modeled on the powerful human cognitive perception processes to extract intelligence from images. Definiens provides organizations with faster image analysis results, allowing deeper insights enabling better business decisions. The company is headquartered in Munich, Germany and has offices in the United States. Further information is available at www.definiens.com.

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