

FOR IMMEDIATE RELEASE

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## **E-BEAM Facilities Quality Management Systems ISO Certified – Including Medical Device and Sterilization Requirements**

E-BEAM Services, Inc. validates its Quality Management System for Medical Devices by attaining ISO 13485 certification and renewing ISO 9001 accreditation at three of its ebeam processing facilities, while also acquiring ISO 11137 certification for Healthcare Product Sterilization at two of the company's plants.



E-BEAM Services renews ISO 9001 certification, while adding ISO 13485 and ISO 11137 certifications for advanced sterilization processing of medical devices at company facilities.

Lebanon, OH – July 23, 2010 – E-BEAM Services, Inc. announced that it has recently fulfilled the necessary requirements to obtain ISO 13485:2003 Quality Management System certifications for Medical Devices, while also renewing the company's ISO 9001:2008 quality accreditation for its facilities in Cranbury, NJ, Lebanon, OH, and Lafayette, IN. In addition, E-BEAM's New Jersey and Ohio plants have obtained ISO 11137-1:2006 [certification of Sterilization Processes](#) for development, validation and routine control for Healthcare Products.

“Electron beam not only offers the most efficient sterilization method for medical products in high volume,” notes E-BEAM Services president Paul Minbiole, “but with these certifications, we also provide third-party validation that our process measures up

to the rigorous quality standards of the healthcare industry.” The three certifications offer E-BEAM’s customers additional assurance of product safety and quality when converting medical device sterilization to the e-beam process, while also providing an ongoing mechanism for monitoring the company’s customer satisfaction and continuous improvement process.

The ISO 9001:2008 certification demonstrates the company’s ability to consistently provide services that meet customer and applicable statutory and regulatory requirements at their facilities. ISO 13485:2003 certifies the promotion and awareness of medical device regulatory requirements, with a focus on risk management, as well corrective and preventative action programs. E-BEAM’s Cranbury, NJ and Lebanon, OH locations received 11137-1:2006 certifications, specific to the controlled application of radiation [sterilization of medical devices](#), as performed at these facilities.

The audit organization and notified body for E-BEAM’s ISO 9001, 13485 and 11137 accreditations is KEMA Quality, a Dekra company headquartered in the Netherlands. KEMA is an internationally-recognized certification organization with a global presence in the healthcare and medical device manufacturing sector.

#### About E-BEAM Services:

E-BEAM Services, Inc. is a leading supplier of contract electron beam processing services for product [sterilization/bioreduction](#) and [polymer product enhancement](#), with more than 450kW of installed accelerator capacity -- enough to process nearly one billion pounds of material annually. E-BEAM was incorporated in 1985 to acquire the radiation service division of a subsidiary of Monsanto and is a privately owned corporation with over 50 employees in Lebanon, OH, Cranbury, NJ and Lafayette, IN. For more information about ebeam sterilization or general information about E-BEAM Services, call 1-877-413-2326 or visit the company’s website at:

<http://www.ebeamservices.com>