

PKG Registers with FDA and Announces Manufacturing Compliance Certification From TÜV SÜD

Certification awarded for the contract design, development, and manufacture of non-implantable OEM system-level medical systems, subassemblies, and components for the areas of diagnostics, imaging, patient treatment, monitoring, and surgical devices



PKG, a privately-owned contract manufacturing and engineering company developing high-end medical and aerospace equipment, announced their registration with the FDA as an establishment producing medical personal protection equipment (PPE), such as surgical masks. PKG also announced the completion of the transfer of its ISO 13485:2016 and ISO 9001:2015 compliance certificates that encompasses the design, development, and production of its devices.

The TÜV SÜD ISO 13485:2016 certification is for the contract design, development, and manufacture of non-implantable OEM system-level medical systems, subassemblies, and components for the areas of diagnostics, imaging, patient treatment, monitoring, and surgical devices. This certification is from TÜV SÜD, one of the few organizations recognized as a designated body under the new European Medical Device Regulation (MDR). It enables PKG to leverage its research, development, and manufacturing strengths for multiple new products addressing novel indications as we advance. TÜV SÜD's MDR designation will also ensure the continuity of regulatory compliance and support post-MDR implementation per European Union Directives on medical devices.

The TÜV SÜD ISO 9001:2015 certification is for the contract design, development, and manufacture of turnkey system-level aerospace, government, and industrial devices with expertise in human-machine interfaces.

"PKG has been diligently working to achieve these milestones for our products manufactured at our factory in Meridian.", said Almir Garibovic, CEO of PKG. "These events continue to strengthen PKG's position as the future leader in state-of-the-art medical device development and manufacture for our customers. We are excited to continue delivering innovative medical devices and enable us to fulfill our vision and values."

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ABOUT TÜV SÜD

TÜV SÜD is a premium quality, safety, and sustainability solutions provider specializing in testing, inspection, auditing, certification, training, and knowledge services. Since 1866, the company has remained committed to its founding principle of protecting people, property, and the environment from technology-related risks. Headquartered in Munich, Germany, TÜV SÜD is represented in more than 1,000 locations worldwide. TÜV SÜD operates globally with a team of more than 24,000 multidisciplinary experts recognized as specialists in their respective fields. By combining impartial expertise with invaluable insights, the company adds tangible value to businesses, consumers, and the environment. TÜV SÜD aims to support customers with a comprehensive suite of services worldwide to increase efficiency, reduce costs, and manage risk. Visit www.tuvsud.com

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