

Press release

Simon Hegele receives ISO 13485 certificate for medical devices at the Raunheim site

With the successful implementation of a quality management system according to DIN EN ISO 13485:2016, Simon Hegele is further expanding its competence in the area of logistics services for manufacturers of medical devices.

Karlsruhe/Raunheim, November 10, 2020. Simon Hegele Gesellschaft für Logistik und Service mbH has successfully had its quality management system at the Raunheim site certified by DQS MED GmbH in accordance with DIN EN ISO 13485:2016. The logistics service provider thus meets the highest regulatory requirements for quality management for medical products. The scope of the certification covers all processes of storage, packaging, conditioning, picking, packing and labelling as well as contract manufacturing including pre-packaging, re-labelling and re-packaging of medical devices.

"This certification confirms that the Raunheim site has a service level of the highest quality standard," says Stefan Ulrich, CEO of Simon Hegele Gesellschaft für Logistik und Service mbH. "For our current and future customers in the medical device industry, we see ourselves as an important strategic partner and offer the decisive framework conditions that our customers need to implement their strategic goals".

Certification according to DIN EN ISO 13485:2016 is a further step for the logistics service provider, which has also been approved by the US authority FDA for several years, to optimally align the Raunheim site to the needs of customers in the medical and safety technology sector.

On 55,000 square meters of logistics space, equipped with permanent temperature and humidity monitoring, different temperature zones, combined with a comprehensive hygiene concept and the use of modern safety technology, Simon Hegele and its nearly 400 highly qualified employees offer highly specialized and comprehensive logistics solutions as a full-service provider. Core services at the location are procurement, production and spare parts logistics as well as associated services such as secure air freight handling, hazardous goods and customs clearance. Customers at the site also benefit from the central traffic location and the immediate vicinity of Frankfurt Airport.

About Simon Hegele Group

The Simon Hegele Group is one of the most innovative service providers along complex supply chain processes. The principle of "more than just logistics..." has been the driving force for the further development of the company group and its services for more than 100 years. Simon Hegele offers customers from the healthcare, industry, IT and retail sectors at over 50 locations worldwide highly specialized value-added services tailored to the respective customer processes and supports them in focusing on their respective core competencies.

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