



————— PRESS RELEASE —————

AMSilk's Quality Management receives certification according to the international medical devices standard DIN EN ISO 13485:2016

Planegg, June 21, 2017 – AMSilk GmbH, the world's first industrial supplier of synthetic silk biopolymers, today announced that its quality management system for the first time has received certification according to DIN EN ISO 13485:2016 by the TÜV Süd. This international standard describes special requirements for quality management systems of medical device manufacturers and their suppliers. With this certification, TÜV Süd confirms that AMSilk is a qualified supplier for medical device manufacturers and that it implements stringent industry standards concerning safety and reliability of its products as well as the required risk management procedures.

Moreover, TÜV Süd recertified AMSilk regarding conformity with the international standard ISO 9001:2015.

Jens Klein, AMSilk CEO, welcomed the certifications as validation of AMSilk's longstanding commitment to quality management: "We are very pleased that our high standards regarding safety and product quality have been reconfirmed by the TÜV certification. As AMSilk is planning to further reinforce and develop its medical technology business unit, especially the certification according to DIN EN ISO 13485:2016 is an essential milestone in the development of best-in-class products."



About AMSilk

AMSilk GmbH is the world's first industrial supplier of synthetic silk biopolymers and has its headquarters in Planegg near Munich, Germany. Sustainably produced using a patented biotechnological process, AMSilk high-performance biopolymers have the unique functional properties of the natural product they are based on. The organic high-performance material can be used in multiple ways, including in medical or technical products as well as cosmetic ingredients. AMSilk high-performance biopolymers give everyday products unique properties. Among other things, the polymers are biocompatible, breathable and especially robust.

AMSilk high-performance biopolymers are distributed in the form of Silkbeads (microparticles), Silkgel (hydrogel) or Biosteel® fibers. They are currently used in coatings for medical technology products, in the textile industry and as an ingredient in cosmetic products.

www.amsilk.com

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