

BellaSeno Granted Market Access in Europe for Custom-Made Bone and Pectus Excavatum Scaffolds

- *Market entry under new EU regulations for medical devices*
- *Spearheading the commercialization of 3D-printed regenerative medicine products*

Leipzig, Germany, July 6, 2023 – BellaSeno GmbH, an ISO 13485-certified medtech company developing resorbable scaffolds using additive manufacturing technologies, today announced that the Company has received authorization for its custom-made bone and pectus excavatum scaffolds in Europe under EU medical devices regulations

The custom-made pectus excavatum scaffolds are among the first 3D-printed regenerative medicine products for surgical use within the plastic and reconstructive surgical field. BellaSeno leverages its proprietary, leading-edge additive manufacturing platform for producing a broad variety of medical scaffolds and implants. The Company has already demonstrated superior mechanical properties of its medical scaffolds, most recently at the European EFORT Congress ([link](#)). BellaSeno's fully automated no-touch manufacturing process allows for high scalability, personalized product characteristics and patient safety.

"We are excited about gaining European market access for our custom-made bone and pectus excavatum scaffolds," said Mohit Chhaya, CEO of BellaSeno. "Clinical data from patients who have received the scaffolds have been very encouraging to date. We are now seeking market authorizations in other geographic regions and for additional products, such as our off-the-shelf breast implants that are suitable for both breast reconstruction and plastic surgery. Our goal is to become a diversified portfolio company and our versatile and sophisticated manufacturing infrastructure puts us in an excellent position to achieve this goal."

"The initial results from the first patients demonstrate that our resorbable implants are safe, well tolerated and increase the potential of autologous tissue grafts," said Dr. med. Tobias Grossner, Chief Medical Officer of BellaSeno. "We are convinced that our approach bears the potential for a paradigm change in regenerative surgery, a field that is in need of innovation to restore complex three-dimensional structures."

BellaSeno's ISO 13485 certified manufacturing platform is designed to meet the requirements of medical scaffolds ranging from soft tissue to bone and enables the production of both custom-made and off-the-shelf sterile medical implants.

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About BellaSeno

BellaSeno GmbH was founded in 2015 and is headquartered on the BioCity campus in Leipzig, Germany, with a subsidiary in Brisbane, Australia. The Company is developing novel resorbable soft tissue and bone reconstruction implants made by additive manufacturing (3D-printing) under ISO 13485 certification. The Company has received substantial financial support from private investors as well as from the Saxony Development Bank (SAB), the European Fund for Regional Development (EFRE), Germany's Federal Ministry of Education and Research (BMBF) and the Australian government. The Company has been co-funded from tax resources based on the budget adopted by the members of Saxony State Parliament.



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Contact BellaSeno

BellaSeno GmbH
Dr. Mohit Chhaya
mohit.chhaya@bellaseno.com
Tel.: +49 176 2283 9583

Media Inquiries

akampion
Dr. Ludger Wess / Ines-Regina Buth
Managing Partners
info@akampion.com
Tel. +49 40 88 16 59 64
Tel. +49 30 23 63 27 68