

Magle Chemoswed Earns CE Mark Approval for SmartPan®

Magle Chemoswed today announced it received CE Mark approval for its first-in-class, advanced medical device technology product, SmartPan®.

SmartPan® is designed by surgeons for use in pancreatic surgery to help surgical teams detect pancreatic juice leakage, which can lead to post-operative complications if left undetected. The patented SmartPan® product is based on Magle Chemoswed's proprietary technology platform and developed in conjunction with a surgical team at Heidelberg University Hospital.

"SmartPan® evidences the potential and versatility of our technology to develop medical devices that have a positive real-world impact on patient outcomes," said Justin Pierce, CEO of Magle Chemoswed.

Magle Chemoswed can market SmartPan® to European hospital systems for use in pancreatic surgical procedures with CE Mark approval. SmartPan® will first be trialed at Heidelberg University Hospital after which Magle Chemoswed will commercialize the product to European hospitals in line with the marketing plan following a stepwise approach.

"CE Mark for SmartPan® is an important milestone for Magle Chemoswed. I am so proud of the team for getting SmartPan® to this stage and I am especially grateful to the team at Heidelberg University Hospital. They have been incredibly collaborative and share equally in the success of the SmartPan® product registration." said Justin Pierce, CEO of Magle Chemoswed.

Now, with CE Mark Approval, SmartPan® can be readily integrated into emerging newer and more advanced methodologies in the field of pancreatic surgery at major hospitals across Europe to make a positive difference to patient outcomes."

Magle Chemoswed holds ISO 134385:2016 certification of its quality management system for medical devices. Under this certification, the Company will manufacture and supply SmartPan™ from the Company facilities in Malmö, Sweden. This certification demonstrates the Company's focus on quality and reflects its ability to provide medical devices that consistently meet customer and applicable regulatory requirements.

Contacts

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About Us

Magle Chemoswed is a unique international contract development manufacturing company dedicated to bringing ideas to product for customers alongside building our own product pipeline based on our patented technology base. As an integrated company, we have extensive capabilities across the value chain, from the discovery, development and manufacture of medicines and medical devices that rely on our patented and trade secret protected technology platform.

Västra Hamnen Corporate Finance is the Company's certified advisor on Nasdaq First North Growth Market and can be reached at ca@vhcorp.se or +46 (0) 40 200 250.

This information is information that Magle Chemoswed is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2021-01-27 16:08 CET.

Attachments

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