

Magle Chemoswed granted CE Mark Approval for SmartGel hydrogel medical device.

Magle Chemoswed today announced it received CE Mark approval for its medical device technology product, SmartGel.

SmartGel is a hydrogel wound dressing indicated for the management of dry to moderately exuding partial and full thickness wounds. The Company has received CE Marking allowing it to be marketed under the brand names of SmartGel and AXXO Woundgel. The AXXO Woundgel brand will be marketed by a distribution partner and shall be manufactured and supplied by Magle Chemoswed. The SmartGel brand will be marketed directly by Magle Chemoswed in Europe.

"We are very excited about SmartGel and the CE Marking is the starting point for our focus on the development and commercialization of a robust and innovative advanced wound care product portfolio in the future," said Justin Pierce, CEO of Magle Chemoswed.

With CE Mark approval Magle Chemoswed can market SmartGel to European hospital systems for use in the professional management of wounds. Magle Chemoswed will commercialize the product to European hospitals in line with the marketing plan following a stepwise approach.

"CE Marking of SmartGel is a further demonstration of the strength and depth of the capabilities of the technology and the highly motivated and driven team members without whom this would not be possible," said Justin Pierce.

Magle Chemoswed holds ISO 13485:2016 certification of its quality management system for medical devices. Under this certification, the Company will manufacture and supply SmartGel and AXXO Woundgel 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 2021-01-28 09:00 CET.

Attachments

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