Press release July 02, 2021, 08.45 CET.

Sedana Medical receives QMS MDR approval

Sedana Medical AB (publ) (SEDANA: FN Stockholm) today announced that the company has received an approval for its quality system (QMS) according to the EU Medical Device Regulation (MDR) 2017/745. The approval means that Sedana Medical's Class I medical device accessories can continue to be sold with CE marking within the EU.

"The new EU Medical Device Regulation (MDR) has been designed to ensure high quality and safety for med tech products and is a real challenge for many companies. Therefore, I am proud of Sedana Medical's efforts to achieve this milestone in our commercialization," said Jens Lindberg, acting CEO of Sedana Medical.

An audit of the processes at Sedana Medical that are affected by the new legal requirements has been performed and approved by Sedana Medical's notifying body.

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Sedana Medical is listed on Nasdaq First North Growth Market in Stockholm.
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About Sedana Medical

Sedana Medical AB (publ) develops and sells the medical device AnaConDa for the administration of volatile anaesthetics. Through a combination of AnaConDa and the drug candidate Sedaconda (isoflurane), Sedana Medical provides inhaled sedation for mechanically ventilated intensive care patients. The company has applied for market approval in Europe for Sedaconda and expects an approval in the second half of 2021.

Today, mechanically ventilated intensive care patients are sedated intravenously which leads to several challenges for both patients and care givers. Challenges that are solved by inhaled sedation. Globally, seven to eight million patients are estimated to be sedated in intensive care due to mechanical ventilation, evenly distributed between the US, Europe, and Asia. These patients are on average sedated three to four days. Sedana Medical estimates the total market potential to SEK 20-30 billion. Three years after marketing approval in Europe, Sedana Medical expects sales of SEK 500 million in Europe and an EBITDA margin of about 40 percent. The company has initiated processes to obtain market approval in the US in 2024 and in markets outside the EU.

Sedana Medical has direct sales in Benelux, France, Germany, Great Britain, the Nordics and Spain as well as external distributors in other parts of Europe, Australia, Canada, China, India, Israel, Japan, Mexico and South Korea. The company was founded in 2005 and is headquartered in Stockholm, Sweden, with medical device development in Ireland.