ICU
MANAGEMENT & PRACTICE

Sedana Medical Receives QMS MDR Approval

SEDANAMEDICAL
Pioneering volatile anaesthetic delivery

Sedana Medical AB (publ) 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.

Published on : Fri, 2 Jul 2021

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