



PRESS RELEASE
March 23, 2022
Gothenburg

XVIVO obtains its first certificate under EU Medical Device Regulation (MDR) for Kidney Assist Transport

Today XVIVO announces an important milestone as the company receives the EU MDR certification for Kidney Assist Transport – a transportable organ perfusion system that allows for continuous oxygenation of kidneys. This signifies that XVIVO B.V.’s quality management system, and the corresponding abdominal product, meet the requirement of the new EU Medical Device Regulation (MDR).

The new Medical Device Regulation (MDR) came into force 2017 and is applicable since 26 May 2021. The new regulation ensures a high level of health and safety protection for EU citizens using medical devices. XVIVO’s Global Quality Assurance & Regulatory Affairs Director Katrin Gisselfält says “This MDR certification is the result of a great team effort and further proof of our commitment to ensure that our products remain available as new regulations go into effect. Receiving the MDR certificate is an important milestone for XVIVO and shows that we are right on track in our efforts to achieve MDR certification for our portfolio”.

In 2020, approximately 16,000 kidney transplants were performed in the EU from deceased donors. However, the number of patients on the waiting list for a new kidney by far exceeds the number of available organs. Followed by the US and China, the EU is the third largest transplant market.

The Kidney Assist Transport is a transportable organ perfusion system that allows for continuous oxygenated perfusion for up to 24 hours and has shown to improve preservation compared to cold storage. Continuous oxygenation is unique to Kidney Assist Transport.

“The Kidney Assist Transport device has the potential to transform the entire kidney transplant market since it shows better survival of transplanted organs and by that makes more kidneys available for transplantation. We already have a strong position within abdominal transplantation in the EU, and by launching Kidney Assist Transport we are strengthening our position even further” says Dag Andersson, CEO of XVIVO.

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Dag Andersson, CEO
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About Us

Founded in 1998, XVIVO is the only medical technology company dedicated to extending the life of all major organs - so transplant teams around the world can save more lives. Our solutions allow leading clinicians and researchers to push the boundaries of transplantation medicine. XVIVO is headquartered in Gothenburg, Sweden, and has offices and research sites on two continents. The company is listed on Nasdaq and has the ticker symbol XVIVO. More information can be found on the website www.xvivogroup.com.

This information is information that XVIVO Perfusion AB 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 2022-03-23 17:45 CET.

Attachments

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