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Hemovent Receives MDR Certification for its MOBYBOX™ ECLS System

New milestone reached: With MDR certification for the MOBYBOX™ system, Hemovent can focus on European-wide expansion of its ECLS product.

AACHEN, Germany, April 2023 — It's done! Hemovent successfully completed the Medical Device Regulation (MDR 2017/745) certification process for its MOBYBOX™ system. The MOBYBOX™ already received the CE mark according to MDD (93/42/EEC) for the European market in 2019. A further step towards future expansion has thus been made.

“We are pleased to see the excellent quality of our product confirmed once again with the successful MDR certification, thus maintaining its validity beyond the MDD certificate. And we are excited that we can now focus on opening up new markets for our ECLS product abroad,” said Dr. Jürgen O. Böhm, CEO & CMO of Hemovent GmbH.

The MOBYBOX™ is the first ECLS device that uses only pneumatic power as its energy source and integrates both blood flow control and gas management into a single device. It does not require complex software and it weighs only 2 kg. The innovative Bionique Flow Technology provides gentle treatment of blood and is unique in ECLS application. So it is not surprising that Hemovent, with its MOBYBOX™, was crowned the winner of the Aachen Innovation Award in 2021. “We are very proud of our successes to date and of our staff, who made all this possible in the first place. It is great to see everyone working towards a joint goal. At the moment, we are concentrating on expanding our portfolio and internationalizing our products. And thanks to our strong team, I am absolutely

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confident that we will continue to successfully accomplish the upcoming projects,” continued Dr. Böhm.

About Hemovent:

Hemovent is an emerging medical device company based in Aachen, Germany that has won multiple awards. Its MOBYBOX™ product is an extremely portable machine that easily fits in a backpack and is even easier to operate. With this highly innovative ECLS system, Hemovent wants to expand the application area of this life-saving technology for heart-lung support to a fully new dimension. Since 2021, Hemovent has been focusing on growth and aims to shape the future of the portable ECLS system market in intensive care medicine over the long term as a member of MicroPort®, a global medical devices company operating in multiple international markets.

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Image materials: Picture of the MOBYBOX™ system