News Release

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Hemovent receives ISO 13485 quality management systems certification as penultimate step in CE mark approval process for its MOBYBOX™ ECMO/ECLS system

AACHEN, Germany, January 09, 2019 — Hemovent GmbH announced today that it has been certified under the ISO 13485:2016 quality management system (QMS) international standard, which management believes is the next-to-last step in the CE marking process for its MOBYBOX system.

MOBYBOX is a self-contained and fully integrated ExtraCorporeal Membrane Oxygenation (ECMO) / ExtraCorporeal Life Support (ECLS) system designed with an ultimate focus on safety, ease of use, mobility, and performance in order to support or replace heart and lung function in the event of cardiac and/or respiratory failure.

"We are proud to be making this announcement, because a full ISO 13485:2016 QMS certification which includes manufacturing, sales and distribution means that Hemovent has demonstrated its ability to provide medical devices that consistently meet customer and applicable regulatory requirements," said Christof Lenz, a co-founder and CEO of Hemovent. "We believe that this certification is the prelude to CE marking for MOBYBOX this year."

Hemovent has previously announced it has successfully completed a GLP standardized in vivo study for long-term (7 days) use of its MOBYBOX system, designed for a wide range of indications: from ExtraCorporeal Life Support (ECLS) to ExtraCorporeal CO2 Removal (ECCO2R).

Hemovent is an emerging medical device company with a proprietary platform technology for heart and lung support.

CAUTION: The Hemovent ECMO/ ECLS System based on Bionique technology is not yet approved for human use.