

Press Release Humedics

Humedics receives ISO 13485 certification

Milestone for market entry of LiMAx test for liver function diagnostics

Berlin, Germany, August 10, 2015 – Humedics GmbH, a specialist for real-time and mobile measurement of the individual liver function at the bedside of the patient, today announced that the company has been certified according to DIN EN ISO 13485. The Quality Management System of the company covers the entire spectrum of processes from design and development, via manufacturing to distribution of its FLIP devices for liver function analysis and corresponding breathing masks. With this certification an important pre-condition for the European marketing of the LiMAx test has been achieved.

Humedics has established a Quality Management System (QMS) according to DIN EN ISO 13485 that covers all processes from design and development, via manufacturing to distribution. The QMS secures a consistently high quality and safety of the FLIP 2.0 analysis device and the corresponding breathing masks. At the same time the certified QMS is a pre-condition for the CE mark of the devices and demonstrates compliance with regulatory requirements. The certification audit was performed by Hamburg-based MEDCERT GmbH.

Erwin de Buijzer, CEO of Humedics GmbH, stated: “After the optimization of our FLIP devices for industrial scale production the ISO certification is an important milestone for the successful market entry of our innovative LiMAx test for liver function diagnostics.” The LiMAx test, together with the corresponding FLIP device and the diagnostic drug offers a clinically proven significant added value for patients with liver diseases and liver surgery.

About Humedics

Humedics has developed a breath test based diagnostic system (LiMAx test), which comprises a CE-marked medical device, breath masks and a diagnostic drug. More than 100 million people world-wide suffer from liver diseases (i.e. cirrhosis, hepatitis, fatty liver, metabolic disorders and liver tumors). The LiMAx test enables the clinician to quantitatively determine the individual liver function capacity for a patient within minutes. This allows for selection of treatment strategies that are optimally adapted to the individual patients liver status. Current applications include diagnosis of the liver function before and after liver transplantation, liver surgery planning (e.g. assessment of the amount of liver to be resected without potentially increasing the risk of liver failure) and assessment of diseases such as liver cirrhosis. The LiMAx test has been used about 14,000 times in clinical practice. Results have been published in highly respected scientific journals. For the approval of the LiMAx test Humedics is presently conducting a phase III multi-center clinical trial. Results are expected in Q IV 2015.

LiMAx Test

The underlying principle of the LiMAx test involves the following steps: Firstly, the diagnostic drug solution is administered intravenously and the drug is metabolized in the liver to paracetamol and ¹³CO₂. The latter is exhaled in the breath. The exhaled air is collected via a breathing mask. Subsequent

continuous measurement of $^{13}\text{CO}_2$ in the patients' breath using laser detection in the FLIP device provides a quantitative determination of the liver capacity and thus reflects the liver function.

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