



GILUPI GmbH Receives ISO 13485 Certification for Manufacturing and Distribution of Cell Separation Devices

After the 68th AACC Annual Scientific Meeting & Clinical Lab Expo (AACC), GILUPI GmbH announces that it has received EN ISO 13485 certification for its German operations. This ISO 13485 certification is an important milestone in the development of the GILUPI GmbH medical device and downstream *in vitro* diagnostics (IVD) business, particularly in the fields of liquid biopsy, molecular diagnostics and clinical oncology.

Dr. Jens Pfannkuche, Managing Director of the GILUPI GmbH, commented: "This is an important step forward for the further growth of our business. Our ISO 13485 certification now allows us to seek market clearance and approval for our liquid biopsy CE-marked medical devices in regulated markets and to manufacture *in vitro* diagnostic kits for downstream molecular diagnostics. Our lead product, the GILUPI CellCollector® Detektor CANCER01 is already being adopted in clinical practice to accumulate circulating tumor cells (CTCs) in the European Union. Together with our partner company Hebei Viroad Biotechnology Co., Ltd. located in China, we are also very excited about achieving Chinese Food and Drug (CFDA) clearance in the near future for oncology use. The certification enables us to fully leverage our current and future B2B channels in Pharma and Diagnostics by broadening their trial protocols and product labels including CTCs next to cell-free tumor DNA and FFPE tissue for their oncology and product pipeline. We expect the emergence of future IVD molecular diagnostic kits referring to our CTC enrichment device due to increased sensitivity for downstream mutation analysis and subsequent selected therapies."

About GILUPI GmbH

GILUPI GmbH is a medical device company founded in 2006 with focus on the development and production of innovative products for the *in vivo* isolation of rare cells from the blood circulation. Currently, the main focus of GILUPI is the diagnostics market for cancer.

Individual oncological targeted therapies will become more and more important in tomorrow's personalized medicine. The identification of the right drug for the specific patient is the upcoming challenge. To address this medical need, the application of the GILUPI CellCollector® enriches rare cells (circulating tumor cells - CTCs) by directly "fishing" them in the patient's bloodstream. By using special diagnostic analyses, these isolated cells can be characterized and/or analyzed at a molecular level.

The GILUPI CellCollector® is the first *in vivo* CTC isolation product worldwide that is CE approved.

For further information visit www.gilupi.com