



## Press Release

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### **Oncobit Achieves ISO 13485 Recertification and Expands IVDR Certification to Cover Additional Indications**

**Zurich, Switzerland - 20.02.2025** - Oncobit, a leading Swiss cancer precision medicine company, proudly announces the successful recertification of its ISO 13485 quality management system, reinforcing its commitment to delivering high-quality and reliable diagnostic solutions. Additionally, Oncobit has expanded its In Vitro Diagnostic Regulation (IVDR) certification to include new indications, further strengthening its position in the field of precision oncology.

ISO 13485 is a globally recognized standard for quality management systems specific to medical devices and diagnostics. The successful recertification underscores Oncobit's dedication to maintaining the highest industry standards in the development and manufacturing of innovative cancer monitoring solutions.

Furthermore, the update of Oncobit's IVDR certificate marks a significant milestone, allowing the company to address additional indications, broadening the accessibility of its personalized monitoring solutions. This regulatory achievement further ensures compliance with stringent European regulations, enhancing patient safety and product reliability.

Having completed the development of prototypes for bladder and colorectal cancer, Oncobit is actively seeking collaborations in these indications. By leveraging its advanced technology and expertise, the company aims to drive forward groundbreaking innovations and provide healthcare professionals with more precise and actionable insights for patient care.

"We are proud to achieve this dual milestone, which underscores our relentless commitment to quality and innovation in precision oncology," said Dr. Claudia Scheckel, CEO of Oncobit. "By expanding our IVDR certification, we are able to bring our cutting-edge monitoring solutions to more patients and are eager to collaborate with partners in the fields of bladder and colorectal cancer to further our impact."

#### **About:**

Oncobit, a leading Swiss cancer precision medicine company, has developed a scalable and data-driven cancer monitoring platform based on the quantitative and sensitive detection of cancer markers in liquid biopsies. By focusing on specific cancer markers that are most relevant, Oncobit provides a cost-effective and time-efficient solution for a tight monitoring of the patient's cancer and an optimized therapy management. Oncobit's cloud-based data analysis and interpretation software was trained on healthy and patient data and ensures a robust and standardized reporting of results. With an initial emphasis on melanoma (already regulatory approved under IVDR), Oncobit has generated significant traction including initial commercial contracts in the pharmaceutical and hospital sectors.

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