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## **Press release**

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### **iO:M8 receives CE-IVD certification**

#### **PreciPoint GmbH launches first microscope for clinical use**

**Freising** – PreciPoint, a German digital microscopy company specializing in digital microscopes and digital pathology solutions, today announced the market launch of its iO:M8 Digital Live Microscope. The microscope is an innovative solution for the digitization of intra-operative examinations during cancer surgery. The device recently received the certification as a CE-IVD product. This first product certification under the new IVDR regulation marks a significant milestone in the corporate development of PreciPoint.

PreciPoint is a young medical technology company and produces solutions for the digitization of microscopy and laboratory processes for applications in medicine, research, and education. The company already collaborates with many prestigious pathologies in Germany in the development of its products. In many government-funded projects, promising approaches in the therapy of numerous cancers are being advanced on the one hand, but at the same time devices are being developed that make these research results visible while simplifying laboratory processes. "Where you live should not define whether you live. The possibilities of digital pathology enable better patient care, and our products facilitate access to digital pathology", explains Dominik Gerber, CEO of PreciPoint GmbH.

The company's latest development, the iO:M8, offers a distinctive solution in the digitization of intra-operative cancer examinations. In these examinations, pathologists determine during surgery whether the tumor tissue has been completely removed from the patient's body and whether the edges of the operated site are free of cancer cells. Traditionally, these examinations are performed at a specific location and time using classical light microscopy. The iO:M8, however, was developed for this specific application. Tissue removed during surgery is cryostatically frozen in a frozen section process, sectioned and applied to glass slides. The iO:M8 can accommodate up to four slides simultaneously. It provides high-resolution, real-time images of the samples while being easy to use. "In view of the ever-increasing shortage of pathologists while the number of cancer cases is rising in Germany, Europe and worldwide, solutions like ours are essential," explains Nicolas Weiss, who heads the company together with Dominik Gerber. Due to its field of application, the iO:M8 is a medical device used for medical therapy. Therefore, the basic principles of safety and performance must be demonstrated for use. Only the CE-IVD marking provides this security.

"We are pleased to announce the launch of our CE-IVD certified iO:M8 digital live microscope, which has passed all necessary tests and regulations to ensure that it meets the highest standards of quality and reliability as IVD medical device. This microscope will help advance digitization in healthcare, and we are excited to see the impact it will have in the medical community", says Gerber. Nicolas Weiss adds: "The CE-IVD certification is a testament to the hard work and dedication of our team, who have put in countless



months to ensure that this microscope meets the highest standards of performance and safety. With this certification, our customers can be least assured that they are getting a safe, reliable, and effective tool for their diagnostic tasks. We are thrilled to be able to bring this cutting-edge technology to the market and contribute to the advancement of MedTech and healthcare.”

**About PreciPoint:**

PreciPoint, a young, future-oriented certified medical technology company (ISO 13485), develops bespoke solutions to bridge the gap between digital workflows and pathologists. The company has developed and marketed fully motorized light microscopes and scanners worldwide with a passion for harnessing the digitization of microscopy in pathology. PreciPoint products include the M8 microscope and scanner, the O8 oil microscope and scanner, and the FRITZ slide scanner. These products generate high-resolution digital images of specimens for review and interpretation by professionals. In addition to hardware products, the company also offers multipurpose software applications and services, including MicroPoint, ViewPoint, PreciCloud, ScanPoint, and ConvertPoint, and other customized solutions for pathologists, researchers, and other microscopy professionals. The company has received numerous awards and recognition, including Top Employer 2023 and Top100 Innovator 2022. PreciPoint was also recognized as a Top Employer for Healthcare Startups.