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Press release

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PreciPoint GmbH successfully certified according to ISO 13485 TÜV Süd confirms quality management system for medical devices

Freising – Seal of quality for medical technology: After successful auditing by TÜV Süd, PreciPoint GmbH, which specializes in digitization solutions in the field of microscopy, has been officially certified according to ISO 13485:2016 since June 2022. This seal certifies that the company's relevant business processes meet the regulatory requirements as a developer and manufacturer of medical devices.

PreciPoint produces solutions for the digitalization of microscopy and laboratory processes for applications in medicine, research, and teaching. The company is already working with many respected pathologies in Germany in the development of its products. These projects not only advance promising approaches in the treatment of numerous cancers but also develop devices that make these research results visible and at the same time simplify laboratory processes. PreciPoint devices must be easy and quick to operate, but at the same time meet the highest scientific requirements.

In 2022, PreciPoint will present the iO:M8 ROSE, a distinctive solution for the digitalization of intraoperative examinations during cancer operations. These examinations, in which pathologists determine during the operation whether enough material has been removed from the patient's body and whether the edges of the operated area are free of cancer cells, are traditionally carried out at a specific location and time using classic light microscopy.

PreciPoint's digital microscope solutions enable completely new ways of working, which enable significant cost savings and faster data exchange among specialists. "In view of the ever-increasing shortage of pathologists and the simultaneous increase in cancer cases in Germany, Europe, and worldwide, solutions like ours are essential," explains Dominik Gerber, who runs the company together with Nicolas Weiss. With the certification according to ISO 13485:2016, another requirement has been met in order to make PreciPoint's products accessible to a larger group of customers in the medical sector. "Together with our employees, we have reached an important milestone that we can be very proud of," says Nicolas Weiss.

PreciPoint:

PreciPoint specializes in the development, production, and marketing of innovative digitization solutions and photonics systems in the field of microscopy. Its product portfolio includes the M8, O8, and FRITZ microscopes. These fully motorized transmitted light microscopes operate digitally and without an eyepiece. They produce high-resolution images of specimens. The microscopes impress with their ease of operation and compact design. They can also be operated from any location thanks to the remote function. PreciPoint offers versatile software applications with which the images can be visualized,



processed, and analyzed. The PreciCloud platform enables new working models between experts. Based in Freising, Germany, PreciPoint is an ISO 13485-certified medical technology company and one of the top startups in Germany. The company has won various awards, including 3rd place as a Top 100 Innovator in 2022. In addition, PreciPoint received awards as an employer in 2021 as well as 2022, for example, as a Top Startup Employer in the healthcare sector by two independent juries.