PRIMAA ANNOUNCES ISO 13485:2016 CERTIFICATION

PRESS RELEASE

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PARIS, FRANCE (September 2021) – Primaa, a medtech company specialized in developing artificial-intelligence based software for histological diagnoses, announced that the company received ISO 13485:2016 certification for Medical Device and Quality Management Systems. This certification is a requirement for regulatory purposes and is an international standard that outlines the requirements for a quality management system specific to the medical devices industry.

ISO 13485:2016 is an internationally recognized quality standard to ensure the consistent design, development, production, installation, and sale of medical devices that are safe for their intended purposes. To be certified, organizations must demonstrate an ability to provide medical devices and related services that consistently meet customer and regulatory requirements.

"*This certification is another evidence of our commitment to quality and allows Primaa to continue to develop our solutions in compliance with the highest standards for safety, product performance and reliability.*" said Fanny Sockeel, CEO for Primaa.

"*Obtaining the ISO13485:2016 certification is a necessary step for our international developments*." replied Anaelle Gallego Garnier, Quality Assurance and Regulatory Affairs Manager for Primaa.

ABOUT PRIMAA:

Paris-based medtech Primaa is developing an artificial-intelligence based tool dedicated to cancer diagnosis. The device is designed to integrate seamlessly into the pathology laboratory infrastructure and automatically analyze breast histological slides to display diagnosis to the pathologist, aiming to increase the turnaround time and decrease the misdiagnosis ratio.
For more information, visit www.primaalab.com or contact.

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