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MIKAJAKI Achieves ISO 13485:2016 Milestone

Inventor of the world's first ophthalmic diagnostic robotic platform

MIKAJAKI has re-engineered eye healthcare by empowering digital, robotics & AI revolutions. This new process includes EyeLib™, a completely self-operated station for comprehensive and automated pre-diagnosis and efficient triage of patients.

Plan Les Ouates, Switzerland — MIKAJAKI, SA announced today that the Company has met another milestone in the company's development with the certification of its quality management system (QMS) under ISO:13485:2016. This certification follows the company's first CE mark (Certificate of Conformity) for the EyeLib™ in September 2020. This achievement means that the company's QMS system meets the most current regulatory requirements specific to the design, manufacturing, and distribution of medical devices.

'The Mikajaki team has worked tirelessly to achieve this ISO certification, often under less-than-ideal circumstances due to COVID-19 restrictions,' said Jacky Hochner, Mikajaki's CEO. 'To achieve ISO:13485, with no major findings or non-conformities, validates this hard work and sets the stage for scaling up manufacturing.'

The first EyeLib is in place at IénaVision Center in Paris, the medical practice of company co-founder, Michael Assouline, MD, PhD. An additional EyeLib is in place at Institut Ophtalmologique de l'Ouest Jules Verne in Nantes, one of the largest ophthalmic centers in Europe. Additional EyeLibs will now be manufactured for partner centers in France and other European countries.

The EyeLib incorporates multiple diagnostic devices into the robotic platform. The fully automated system allows patients to check in with their insurance card, identify themselves and then move onto the EyeLib for testing. The information gathered is then safely transmitted to the clinic's EMR system for use by the ophthalmologist and clinic staff.

With ISO:13485 certification in place, Mikajaki's team of experienced robotic, software and AI experts is now focused on delivering the pre-orders for partner centers in France and Europe.

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About MIKAJAKI, SA: Michael Assouline, MD, PhD, together with Jacky Hochner, founded MIKAJAKI in 2018 with the vision to re-engineer the eye healthcare diagnostics process. They've used their combined 25 years of experience in surgical practice and ophthalmic device commercialization, to design a revolutionary approach to ophthalmic diagnostics. Thanks to their extensive network of professionals, Michael and Jacky have succeeded in rapidly setting up critical engineering, medical, manufacturing and financial partnerships, which support their project. MIKAJAKI is based in Plan les Ouates in the HI Flow building following its incubation as part of the FONGIT.

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