



Mauna Kea Technologies Announces CE MDR Certification For Cellvizio® and Its Associated Probes

A major regulatory milestone in the European commercial expansion strategy

Mauna Kea Technologies is the only endomicroscopy company to obtain this certification under the new European regulation

Paris and Boston, February 10, 2026 – 5:45 p.m. CET – Mauna Kea Technologies (Euronext Growth: ALMKT), inventor of Cellvizio®, the multidisciplinary probe and needle-based confocal laser endomicroscopy (p/nCLE) platform, today announces that it has received certification of conformity to the European Medical Device Regulation (MDR 2017/745) for its entire Cellvizio system and range of probes.

This certification was issued by GMED, a leading and highly demanding notified body in the sector. It confirms that the Cellvizio platform meets the strictest international criteria for safety, performance, and clinical performance. This marking ensures the long-term commercialization of Cellvizio within the European Union and countries that recognize the CE mark and paves the way for the deployment of new clinical applications as well as the future integration of Artificial Intelligence solutions within the current regulatory framework.

Sacha Loiseau, Ph.D., Chairman and CEO of Mauna Kea Technologies, commented: *"The transition to MDR represents one of the most severe challenges the MedTech sector has ever faced in Europe. Obtaining this certification proves once again the excellence of our quality processes and the clinical superiority of Cellvizio. It is a powerful catalyst in our European commercial expansion strategy across our two high-potential clinical areas: pancreatic cysts and food intolerances (CellTolerance)."*

About Mauna Kea Technologies

Mauna Kea Technologies is a global medical device company that manufactures and sells Cellvizio®, the real-time in vivo cellular imaging platform. This technology uniquely delivers in vivo cellular visualization which enables physicians to monitor the progression of disease over time, assess point-in-time reactions as they happen in real time, classify indeterminate areas of concern, and guide surgical interventions. The Cellvizio® platform is used globally across a wide range of medical specialties and is making a transformative change in the way physicians diagnose and treat patients. For more information, visit www.maunakeatech.com.

Mauna Kea Technologies

investors@maunakeatech.com

NewCap - Investor Relations

Thomas Grojean

+33 (0)1 44 71 94 94

maunakea@newcap.eu



Disclaimer

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