

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.

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Disclaimer

This press release contains forward-looking statements about Mauna Kea Technologies and its business. All statements other than statements of historical fact included in this press release, including, but not limited to, statements regarding Mauna Kea Technologies' financial condition, business, strategies, plans and objectives for future operations are forward-looking statements. Mauna Kea Technologies believes that these forward-looking statements are based on reasonable assumptions. However, no assurance can be given that the expectations expressed in these forward-looking statements will be achieved. These forward-looking statements are subject to numerous risks and uncertainties, including those described in Chapter 2 of Mauna Kea Technologies' 2024 Annual Report filed with the *Autorité des marchés financiers* (AMF) on April 30, 2025, which is available on the Company's website (www.maunakeatech.fr), as well as the risks associated with changes in economic conditions, financial markets and the markets in which Mauna Kea Technologies operates. The forward-looking statements contained in this press release are also subject to risks that are unknown to Mauna Kea Technologies or that Mauna Kea Technologies does not currently consider material. The occurrence of some or all of these risks could cause the actual results, financial condition, performance or achievements of Mauna Kea Technologies to differ materially from those expressed in the forward-looking statements. This press release and the information contained herein do not constitute an offer to sell or subscribe for, or the solicitation of an order to buy or subscribe for, shares of Mauna Kea Technologies in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. The distribution of this press release may be restricted in certain jurisdictions by local law. Persons into whose possession this document comes are required to comply with all local regulations applicable to this document.