



Press release – For immediate release

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## Median Technologies achieves ISO 13485:2016 certification for eyonis® Medical Device Quality Management System

- Certification of a robust and compliant Quality Management System for AI-based Software as Medical Devices, as per internationally recognized medical device regulatory standards
- Pledge of quality to support the industrialization, scaling, and deployment of Median’s eyonis® Software as a Medical Device portfolio
- Key milestone to pursue future regulatory approvals for the eyonis® portfolio and to deliver safe, reliable, and clinically meaningful oncology solutions

**Sophia-Antipolis, France** : Median Technologies (*FR0011049824, ALMDT, “Median” or the “Company”*), developer of eyonis®, a suite of artificial intelligence (AI)-powered Software as a Medical Device (SaMD) solutions for early cancer diagnosis, and a globally leading provider of AI-based image analyses and central imaging services for oncology drug developers, today announced it has achieved the globally recognized ISO 13485:2016 certification for its Quality Management System (QMS) applicable to AI-based Software as Medical Devices.

The ISO 13485:2016 certification, granted by the French accredited notified body GMED, encompasses the full scope of activities of Median’s eyonis® business unit, including the design, development, deployment, sales and maintenance of AI-based SaMD. This certification confirms the Company’s ability to industrialize and scale eyonis®, its portfolio of advanced SaMD, in accordance with the latest State of the Art and applicable regulatory requirements.

*“2026, which is set to be a pivotal year for Median Technologies and builds on last month’s FDA 510(k) clearance and commercial launch of eyonis® LCS, continues on a positive trajectory with the achievement of ISO 13485:2016 certification, which validates the strict quality framework supporting eyonis®, our AI-based SaMD portfolio”, said **Fredrik Brag, Founder and Chief Executive Officer of Median Technologies.** “This certification marks a key milestone while strengthening our readiness for future regulatory authorizations for the eyonis® portfolio of solutions, including the expected CE marking of eyonis® LCS in Q2 2026. It further underscores our ability to deliver safe, reliable, and clinically meaningful oncology solutions that meet the stringent requirements of healthcare professionals and regulatory authorities worldwide.”*

The Company’s ISO 13485:2016 certification adds to the compliance cycle started with the ISO 27001:2022 and HDS 2.0 certifications obtained in 2025. Together, these certifications demonstrate the robustness and high level of quality of Median’s QMS for Software as a Medical Device, its ability to manage sensitive data, and the Company’s ongoing commitment to operational excellence and continuous improvement.

**ALMDT****EURONEXT****GROWTH**

**About Median Technologies:** Pioneering innovative software as a medical device and imaging services, Median Technologies harnesses cutting-edge AI to enhance the accuracy of early cancer diagnoses and treatments. Median's offerings include iCRO, which provides medical image analysis and management in oncology trials, and eyonis®, an AI/ML tech-based suite of software as a medical device (SaMD). Median empowers biopharmaceutical entities and clinicians to advance patient care and expedite the development of novel therapies. The French-based company, with a presence in the U.S.

and China, trades on the Euronext Growth market (ISIN: FR0011049824, ticker: ALMDT). Median is also eligible for the French SME equity savings plan scheme (PEA-PME). For more information, visit [www.mediantechologies.com](http://www.mediantechologies.com).

## Contacts

### **MEDIAN TECHNOLOGIES**

**Emmanuelle Leygues**

VP, Corporate Marketing & Financial Communications

+33 6 10 93 58 88

[emmanuelle.leygues@mediantechnologies.com](mailto:emmanuelle.leygues@mediantechnologies.com)

### **Investors - SEITOSEI ACTIFIN**

**Ghislaine Gasparetto**

+33 6 85 36 76 81

[ghislaine.gasparetto@seitosei-actifin.com](mailto:ghislaine.gasparetto@seitosei-actifin.com)

### **Press – MAARC**

**Bruno Arabian**

+33 6 87 88 47 26

[bruno.arabian@maarc.fr](mailto:bruno.arabian@maarc.fr)

**Nicolas Entz**

+33 6 33 67 31 54

[nicolas.entz@maarc.fr](mailto:nicolas.entz@maarc.fr)

### **U.S. media – TODD STEIN COMMUNICATIONS**

**Todd Stein**

+1 510.417.0612

[todd@toddsteincommunications.com](mailto:todd@toddsteincommunications.com)

## Forward-Looking Statements

This press release contains forward-looking statements. These statements are not historical facts. They include projections and estimates as well as the assumptions on which these are based, statements concerning projects, objectives, intentions, and expectations with respect to future financial results, events, operations, services, product development and potential, or future performance.

These forward-looking statements can often be identified by the words "expects," "anticipates," "believes," "intends," "estimates" or "plans" and any other similar expressions. Although Median's management believes that these forward-looking statements are reasonable, investors are cautioned that forward-looking statements are subject to numerous risks and uncertainties, many of which are difficult to predict and generally beyond the control of Median Technologies, that could cause actual results and events to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements.

All forward-looking statements in this press release are based on information available to Median Technologies as of the date of the press release. Median Technologies does not undertake to update any forward-looking information or statements, subject to applicable regulations, in particular Articles 223-1 et seq. of the General Regulation of the French Autorité des Marchés Financiers.