

# Tracey Technologies' Achieves EU Medical Device Regulation (MDR) Certification

*Tracey Technologies announced that the company has successfully achieved certification for the iTrace under the European Union's Medical Device Regulation.*

HOUSTON, TX, UNITED STATES, February 10, 2025 /EINPresswire.com/ -- [Tracey Technologies](#),



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*Ray Sievert, EVP Sales & Marketing*

manufacturer of the [iTrace](#) 5-in-1 visual diagnostic device and a global leader in ophthalmic technology, announced that the company has successfully achieved certification under the European Union's Medical Device Regulation (MDR). This significant milestone verifies compliance with the EU's stringent regulatory requirements, enabling continued distribution of the iTrace across European markets.

The MDR, which replaced the previous Medical Device Directive (MDD), imposes more rigorous standards on

medical device manufacturers to ensure the highest levels of safety, quality, and clinical efficacy. Tracey Technologies' successful certification underscores the company's commitment to regulatory excellence and patient safety.

"This has been a years-long effort for us, and very few companies of our size have reached this goal," said Ray Sievert, EVP of Sales and Marketing at Tracey Technologies. "The iTrace also moved from a Class I Measuring device to a Class IIa classification during this process, demonstrating our ability to meet higher regulatory standards and reflecting the robustness of our quality management systems."

The iTrace utilizes proprietary Ray Tracing technology to obtain advanced real-time data on a patient's vision and precise measurements of the eye's internal and external anatomy. It assists ophthalmologists and cataract surgeons in diagnosing and treating a range of vision issues, helping them optimize patient outcomes in cataract and refractive surgeries and meet the needs of their patients. The iTrace's novel approach enables clinicians to differentiate between corneal and internal aberrations, allowing for precise pre-surgical planning, exact post-surgical lens adjustments, and customized treatment strategies for patients.

The transition to MDR compliance represents a significant investment in Tracey Technologies' global strategy. The rigorous evaluation process included an in-depth review of the company's quality management system, clinical data, post-market surveillance, and risk assessment protocols. Additionally, compliance with MDR mandates continuous monitoring and adaptation to regulatory updates, ensuring the iTrace maintains the highest quality and safety standards in the market.

Compliance with MDR regulations also reinforces the company's ability to expand its market presence in Europe, enabling more eye care professionals to access cutting-edge diagnostic technology for improved patient outcomes.

"Achieving MDR certification not only enables us to continue serving our European customers but also reinforces the trust that cataract surgeons have in our technology," Sievert added. "We are proud of our team's hard work in meeting these enhanced regulatory requirements and look forward to continuing our mission of improving patient care through advanced diagnostics."

With this certification, Tracey Technologies remains well-positioned to support eye care professionals in delivering high-quality care across Europe and beyond. The company will continue to innovate and enhance the iTrace's capabilities while ensuring adherence to evolving regulatory standards worldwide. In the coming years, Tracey Technologies aims to further expand its footprint in global markets by leveraging its strong regulatory framework, innovative technology, and commitment to excellence in ophthalmic diagnostics.

#### About the iTrace

Tracey Technologies developed the iTrace more than a decade ago to help uncover the underlying causes of "vision mysteries," educate patients, and precisely plan a range of vision correction procedures. As the only device to use true Ray Tracing to objectively measure the way light enters the eye, top cataract and refractive surgeons have relied on the iTrace to help them provide the best possible outcomes to their patients for many years. To learn more about the iTrace, visit [www.traceytechnologies.com](http://www.traceytechnologies.com).

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