

FormaTK Systems Achieves Full EU MDR Certification – Reinforcing Commitment to Quality and Innovation

TIRAT CARMEL, HAIFA DISTRICT, ISRAEL, July 21, 2025 /EINPresswire.com/ -- FormaTK Systems Ltd., a global developer and manufacturer of advanced aesthetic medical technologies, proudly announces that it has been officially certified under the European Medical Device Regulation (EU MDR 2017/745), meeting the most rigorous standards for safety, performance, and clinical efficacy.

This important milestone reflects FormaTK's enduring commitment to designing and producing technologies that meet the evolving needs of modern aesthetic clinics while ensuring full compliance with global regulatory frameworks.

"Achieving MDR certification is a testament to our team's relentless focus on clinical quality and patient safety," said Shai Toledano, CEO of FormaTK Systems. "It reinforces our ongoing commitment to delivering innovation with integrity, meeting the highest standards while empowering clinics worldwide with safe, effective, and easy-to-use technology."

FormaTK's MDR certification applies to its entire portfolio of technologies, which includes a third-generation Diode Laser designed for fast and safe hair removal across all skin types, and a proprietary 3D IPL platform that enables intelligent light delivery with refined control over pulse configuration and cooling.

The ND:YAG 1064 nm laser delivers targeted vascular treatments and deeper thermal effects, making it ideal for addressing leg veins, facial vessels, and skin tightening procedures with precision and safety.

SMART ST technology harnesses thermal energy to trigger collagen regeneration and visibly firm the skin, while R-SONIC uses ultrasound-based energy to improve product absorption and enhance dermal rejuvenation. Lastly, the DIAMOND PEELING device offers gentle mechanical exfoliation to polish and refresh skin tone and texture.

These technologies are deployed within FormaTK's flagship platforms: Alpha, Magma, Forma, and Forma Light, which together offer practitioners modular treatment solutions tailored to the evolving needs of today's aesthetic market.

"FormaTK's MDR approval assures our German clients, and the broader European market, that

they are working with a fully certified and clinically validated company," said Manuel Reimer, CEO of Amaderm GmbH, FormaTK's representative in Germany. "This certification enhances trust and expands access to safe, high-performing medical aesthetic systems."

With this achievement, Formatk is poised to expand further across European and international markets that require MDR certification, deepening partnerships and increasing practitioner confidence worldwide.

For more information about FormaTK's certified technologies and systems, visit: www.forma-tk.com

ABOUT FORMATK SYSTEMS LTD.

Established by industry veterans, FormaTK brings a wealth of over 17 years of R&D experience together with a fresh and market-oriented approach. The company is inspired to deliver better results by developing technologies that empower today's clinics.

The company proudly partners with professional practitioners in 45 countries and counting. With these quality-based relationships, the company has successfully developed a brand built on the commitment to deliver excellence.

ABOUT AMADERM

Amaderm GmbH is a trusted provider of premium aesthetic technologies across Germany and Austria. With over a decade of industry experience, the company is known for its commitment to rigorous product testing, transparent customer service, and a strict focus on clinically effective devices. Amaderm partners only with globally recognized manufacturers, delivering proven solutions without inflated promises or hidden compromises.

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