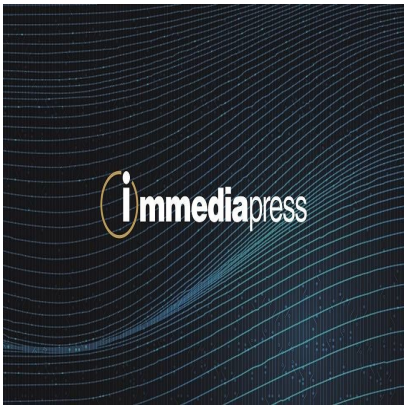

FDA Qualifies MolecuLightDX Wound Measurement as a Medical Device Development Tool (MDDT) for Evaluating New Products in Wound Care

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

PITTSBURGH, Jan. 29, 2026 /PRNewswire/ â?? MolecuLight today announced that its MolecuLightDXÂ® wound measurement has been qualified by the U.S. Food and Drug Administration (FDA) as a Medical Device Development Tool (MDDT). The FDAâ??s MDDT program qualifies select, scientifically validated tools for use in medical device development and evaluation, enabling sponsors to generate reliable, FDA accepted data in clinical investigations.

With MDDT qualification, the MolecuLightDX quantitative wound measurement function is validated for regulatory use as a response biomarker, supporting objective evaluation of treatment effectiveness and data generation that may be used in FDA clearance and approval decisions for new wound products. Since the program began in 2017, MDDT qualification has been granted to only 20 tools, including MolecuLightDXÂ®.

MolecuLightDX is the only wound care device that is both FDA Class II cleared for clinical use and FDA qualified as an MDDT, providing accurate, non-contact, and reproducible wound measurement images and data suitable for clinical trial endpoints across a variety of wound types.

â??The FDAâ??s qualification of MolecuLightDX as an MDDT reflects the strength of our clinical evidence and the agencyâ??s confidence in the accuracy and reproducibility of our wound measurement technology,â?• said Anil Amlani, Chief Executive Officer of MolecuLight. â??This designation enables researchers and sponsors to use MolecuLightDX as a standardized, trusted measurement tool in wound healing studies, accelerating innovation and improving patient outcomes.â?•

MolecuLightDX is class II FDA-cleared medical device for the real-time detection and visualization of elevated bacterial loads (>10â•´ CFU/g) in wounds using its proprietary fluorescence imaging technology. Its performance is supported by the largest clinical validation study conducted in wound imaging, demonstrating consistent results across wound types, skin tones, and patient populations.

About MolecuLight

MolecuLight is a privately held medical imaging company with a global footprint, dedicated to manufacturing and commercializing the MolecuLight i:XÂ® and DXÂ® wound imaging devices. Both FDA-cleared Class II point-of-care systems provide real-time detection of elevated bacterial burden and accurate digital wound measurement. The MolecuLightDXÂ® additionally offers thermal imaging for comprehensive wound assessment. The technologiesâ?? effectiveness and clinical utility are supported by more than 100 peer-reviewed publications.

For sales, media or other inquiries or further information, please contact: MolecuLight: Danielle Dunham, Director of Product and Marketing, T. +1.416.542.5524, ddunham@moleculight.com, www.moleculight.com

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