Under embargo till 25 January 2024

Envisionit Deep AI®'s Chest x-ray AI medical device, RADIFY® Triage and notification software, achieves 510(k) FDA clearance.

London, 25 January 2024 — Envisionit Deep AI®, a leading innovator in artificial intelligence diagnostic radiology solutions, is thrilled to announce the successful receipt of a 510(k) FDA clearance for its AI assisted chest x-Ray solution, RADIFY®, under two critical pathologies. Envisionit Deep AI®'s RADIFY® Triage has officially been cleared to triage Pneumothorax and Pleural Effusion, 2 critical findings that represent significant challenges in emergency rooms and intensive care units.

RADIFY® showed significant clinical accuracy in triaging both pathologies, within an average of 3 seconds to alert healthcare professionals. RADIFY®'s combined speed and accuracy positions it as an essential medical device to enhance the efficiency and effectiveness of medical professionals in emergency rooms and intensive care units. Envisionit Deep AI® was established with a commitment to ethical AI principles. In alignment with this philosophy and to mitigate potential biases in AI, RADIFY® underwent a thorough evaluation using diverse data and pertinent subgroup analysis through RATify, a standalone AI Validation and Quality Assurance tool in the company's product suite. All the safety parameters of the device were verified in accordance with the software specifications and applicable performance standards and met the acceptance criteria (Device shows > 95% AUC).

"In collaboration with Hardian Health, Envisionit Deep AI® diligently showcased the device's capacity to fulfil precise regulatory benchmarks. The rigorous FDA clearance process involved thorough clinical testing and evaluations, affirming the device's adherence to the utmost standards of accuracy and safety. Moreover, RADIFY® was *one of the first companies* that underwent a meticulous evaluation against the FDA's *new* robust cybersecurity, rendering the approval even more gratifying." Hugh Harvey, Managing Director Hardian Health.

"RADIFY®'s ability to quickly triage pneumothorax and pleural effusion significantly reduces the time taken to alert ER doctors to critical pathologies that require urgent attention. This innovative solution is a game changer that will enhance the efficiency of doctors leading to better patient care", said Dr. Steven Holt, CEO, First Care Solutions.

"We are excited and proud to receive a 510(k) FDA clearance for RADIFY®. This certification reaffirms Envisionit's dedication to providing cutting edge technologies that elevate patient care and contribute to improved healthcare outcomes. At Envisionit Deep AI® our commitment to innovation extends beyond just AI solutions, it encompasses ethical considerations and real-time validation as integral components of our mission to advance diagnostic healthcare. The timing of this regulatory

approval coincides perfectly with Envisionit Deep AI's imminent capital raise." said Dr Jaishree Naidoo, CEO at Envisionit Deep AI®.

Envisionit Deep AI® remains at the forefront of technological advancements in healthcare, continually striving to push the boundaries of what is possible. With a 510(k) FDA clearance in hand, Envisionit Deep AI® is poised to make a lasting impact on the medical imaging diagnostic landscape.

For more information about RADIFY® or Envisionit Deep AI®, please visit www.envisionit.ai

About Envisionit Deep AI®:

Envisionit Deep AI® is a leading artificial intelligence medical device company dedicated to transforming healthcare through innovative technologies. With a commitment to ethical ai development and excellence, Envisionit Deep AI® strives to improve patient outcomes and enhance the efficiency of healthcare delivery. For more information, visit www.envisionit.ai .

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