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Inito clears USFDA regulatory pathway for fertility monitor

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Initoâ??s Fertility Monitor is a small device that enables smartphones to perform lab-grade fertility diagnostic tests at home â?¨



Inito, a Bengaluru-based medical technology startup, has announced that its Fertility Monitor has cleared the regulatory pathway of the United States Food and Drug Administration (FDA). By clearing this, Inito has become the first designed, engineered and manufactured in India home diagnostic device to achieve this milestone.

Inito's Fertility Monitor is a small device that enables smartphones to perform lab-grade fertility diagnostic tests at home. By measuring two fertility hormones in urine - Estrogen & Luteinizing Hormone (LH) – along with AI based data analytics in the App, Inito understands the cycle variations for every individual user, giving highly accurate results unique to every woman's body.

Over the course of more than a year, Inito's flagship device has been subjected to a series of clinical studies, manufacturing facility setup tests as per GMP standards, and company-wide Quality Management System, ensuring the reliability and efficacy of the device.

"Inito has always been committed to building a global home diagnostic testing company headquartered out of India, and this milestone takes us one step closer to that ambition. The coming years will see home diagnostics become an integral part of the medical ecosystem, and we're proud to be among the leaders of this revolution," said Aayush Rai, Co-Founder, Inito. "Clearing the FDA regulatory pathway speaks to the commitment and dedication of our team, who have upheld the highest standards of engineering, user experience, and clinical validation throughout the course of development," he added.

Inito's patented 'Flat-lens' technology allows dozens of diagnostic tests for fertility, diabetes, Vitamin D, Thyroid etc. and more on a single device connected to a smartphone. A study by IIT Delhi determined the device to achieve a 99.12 per cent correlation with clinical-grade instrumentations which cost up to 100 times more and are 10 times bigger. As of now, the device supports fertility tests and other tests like Diabetes, Thyroid and Vitamin D tests are soon to be added to the device.