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Forus Health secures CDSCO approval for AI-led Diabetic Retinopathy screening tool

04 February 2026 | News

Supporting earlier clinical evaluation and timely intervention to help prevent diabetes-related vision loss



Bengaluru-based medtech firm Forus Health has received regulatory approval from the Central Drugs Standard Control Organization (CDSCO) for its FH-POISE™ DRT (Diabetic Retinopathy Tools).

FH-POISE™ (Precision Ocular Intelligence for Systemic & Eye Health) is Forus Health's AI-powered retinal image analysis platform designed to support the detection and screening of ocular and systemic diseases using state-of-the-art algorithms.

The approval enables FH-POISE™ DRT to be used as a screening tool to identify patients at risk of diabetic retinopathy, supporting earlier clinical evaluation and timely intervention to help prevent diabetes-related vision loss. The software uses deep learning models to assess retinal images and predict disease severity, allowing for more nuanced and clinically relevant screening outcomes.

It has received CDSCO approval as Class C SaMD (Software as a Medical Device), one of the most stringent risk categories, with the approach validated on real-world retinal images, spanning a diverse demography, demonstrating suitability for real-world healthcare settings.

India carries one of the world's largest diabetes burdens. According to the International Diabetes Federation, approximately 89.8 million adults in India were living with diabetes in 2024, placing sustained pressure on the healthcare system.

"India's challenge with diabetic retinopathy is not awareness alone, but scale," said Chandrasekhar K., Founder and CEO, Forus Health, "Embedding reliable screening into routine diabetes care is essential if we are to prevent avoidable vision loss. Regulatory approval for FH-POISE™ DRT enables technology-focussed screening closer to where patients already receive care, helping strengthen early detection while making better use of limited specialist capacity."

The broader economic impact of vision impairment further underscores the importance of early detection. Peer-reviewed studies estimate that vision impairment and blindness in India result in productivity losses exceeding Rs 11,000 crore annually, highlighting the societal cost of delayed diagnosis and treatment.

With CDSCO approval in place, Forus Health plans to deploy FH-POISE™ DRT across hospitals, public health initiatives, and screening programs, aligned with India's focus on preventive healthcare and digital health-enabled early diagnosis.