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13 December 2013 | News | By BioSpectrum Bureau

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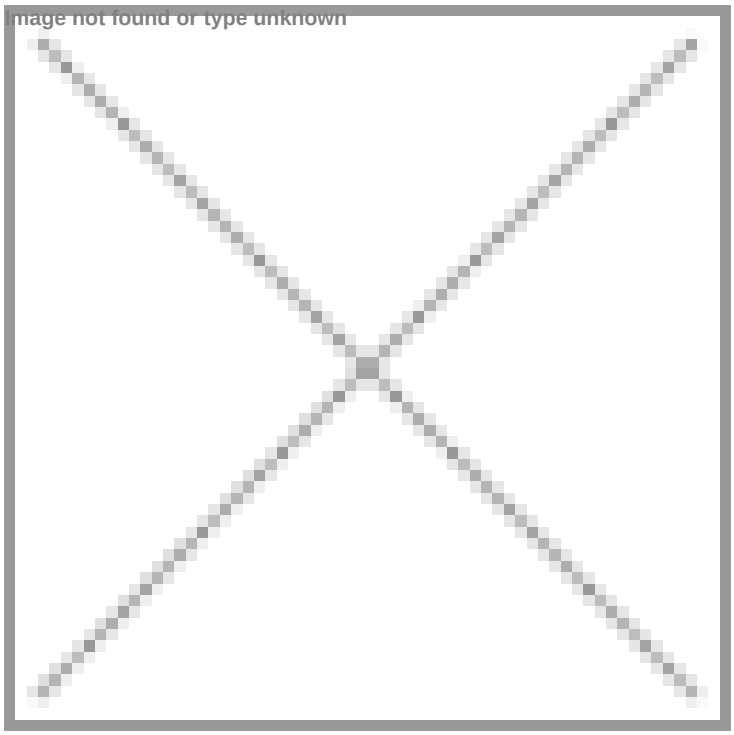

To help Indian small and medium enterprises (SMEs) achieve access to global markets, UL, a worldwide leader in advancing safety, announced that Bangalore-based medical devices startup, Forus has been issued the prestigious ISO 13485 certification.

The standard ensures compliance of various aspects of a product lifecycle that affect safety and effectiveness of medical devices, including product design, prototype, manufacturing, installation, service and market surveillance of installed products. This enhances the credibility of Forus regulated markets, kicking off Forus' endeavor to penetrate markets outside India.

The medical device sector in India is witnessing a surge of start-ups keen on addressing the huge gap in healthcare access, and increasing their revenue potential from global markets. UL works with over 70 SMEs and start-ups in this sector.

"We are delighted about the ISO 13485 certification which confirms the compliance of standards and manufacturing process quality and innovation. Working with UL gave us a lot of insights into how regulatory compliance has to be a part of the product DNA itself, and not something that adds up at the end. The early-engagement program of UL greatly helped us understand what was involved in making our product ready, not just for India, but for various global markets as well', said Dr Shyam Vasudevarao, president & CTO Forus.

Forus is a pioneer of frugal innovation in ophthalmology, and its product, 3nethra is the world's first inexpensive, portable, ophthalmic pre-screening device. By identifying five major eye ailments, 3nethra negates the deployment of multiple, expensive devices.

Forus has installed over 220 3nethras and is planning to exceed 400 installations in the next 6-9 months. The ISO 13485 certification, was received in seven months since the quality system effort was initiated.

To maintain this certification, company personnel involved in the product lifecycle must be committed to readiness and compliance. Going forward, Forus will engage with UL for their upcoming certification and regulatory requirements for various global markets.

On the Forus milestone, Mr Suresh Sugavanam, MD, UL India and South Asia said, "UL has extensive experience across all global markets, and a deep understanding of the complexities of various regulations. In the last few years, we have seen a huge appetite among Indian SMEs and start-ups for accessing global markets. In India, UL's key goal is to demystify global regulations through early engagement in product lifecycle and certify compliance thereto. In our engagement with Forus, we were witness to a high level of commitment and drive from the management to spearhead efforts towards regulatory compliance."

ISO 13485, "Medical devices -- Quality management systems -- Requirements for regulatory purposes" is the globally recognized quality systems standard that helps organizations ensure the consistent manufacturing of their medical devices. An ISO13485 certification through an accredited third party registrar certifies an organization's compliance with the standard leading to enhanced credibility in regulated markets.