

Exosome Diagnostics Achieves ISO 13485:2016 Certification

Due to demand for the company's instrument platform and companion diagnostic tests, Exosome Diagnostics continues to grow as an In Vitro Diagnostic (IVD) manufacturer.

WALTHAM, MA – June 13, 2018 - Exosome Diagnostics, Inc. announced that it has achieved ISO 13485:2016 certification for their Munich location, upgraded from the ISO 13485:2003 certificate. This certification paves the way for Exosome Diagnostics as an In Vitro Diagnostic (IVD) medical device design and manufacturing organization. Combining the company's CLIA certified laboratory in Waltham and the ISO 15189 accredited laboratory in Munich, serves as an integral part of the company's strategy for across the board development of the instrument, diagnostics and companion diagnostics platforms.

"This ISO 13485:2016 certification is a testament to the compliance initiatives undertaken by Exosome Dx to design and manufacture IVDs. Working closely with the notified body registrar and appropriate regulatory agencies, Exosome Dx adheres to the strictest standards to ensure that the highest quality products are provided to clinicians," stated Raaj Venkatesan, Head of Regulatory Affairs at Exosome Diagnostics. "Exosome Diagnostics has built a high-quality team of dedicated engineers, managers, regulatory professionals and scientists who have placed quality and process as their number one priority," Venkatesan continued.

Exosome Diagnostics manufactures its proprietary isolation platforms for exosome isolation, including ExoLution, ExoLution Plus and ExoLution UPrep, to isolate exosomes from various biofluids such as blood, plasma, serum, urine and cerebrospinal fluid. Exosome Diagnostics also offers diagnostic assays under its CLIA and ISO 15189 certified locations in Waltham and Germany.

"Exosome Diagnostics' upgraded certification to the ISO 13485:2016 standard shows our unwavering commitment to regulatory compliance" stated John Boyce, President and CEO of Exosome Diagnostics. "With the ISO 13485:2016 certification, the company can continue advancements in the design and development of IVDs and CE marking them for early stage disease detection," Boyce continued. "The ISO 13485:2016 certification is an essential part of the company's strategy and is a testament to the teams in both the USA and Germany that worked diligently to achieve this certification," stated Boyce.

About Exosome Diagnostics

Exosome Diagnostics is a privately held company focused on developing and commercializing revolutionary biofluid-based diagnostics to deliver personalized precision healthcare that improves lives. The company's novel exosome-based technology platform, ExoLution™, can yield comprehensive and dynamic molecular insights to transform how cancer and other serious diseases are diagnosed, treated and monitored.

Visit www.exosomedx.com to learn more.

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Media Contact

Amelia Groeneveld

agroeneveld@exosomedx.com

(917) 455-6259