

ProteoMediX receives ISO 13485:2012 Certification

Zurich-Schlieren, Switzerland, January 13, 2017. ProteoMediX AG, a diagnostic company producing non-invasive in vitro diagnostic assays for prostate cancer diagnosis, has been awarded ISO 13485:2012 certification.

ProteoMediX is proud to announce that it has been awarded ISO 13485:2012 certification for the “Design, development, control of production, and distribution of in vitro diagnostics for prostate cancer”. This will allow ProteoMediX to advance the development and commercialization of diagnostic tools to improve the early diagnosis and prognosis of prostate cancer and provide urgently needed diagnostic tests that support patients and physicians in their decision making.

“This certification represents a major milestone in the development of our current in vitro diagnostic test for the improved diagnosis of prostate cancer as well as for future products in our pipeline. It highlights the commitment of ProteoMediX to provide products of the highest level of safety, quality and usability,” said Dr. Ralph Schiess, CEO.

ISO (International Organization for Standardization) 13485:2012 is an international standard specific to the requirements of a quality management system for the design and manufacture of medical devices and in vitro diagnostic tests. ProteoMediX is certified by TÜV SÜD Product Service GmbH, an internationally recognized notified body in Germany. Implementation of ISO 13485:2012 is a prerequisite for obtaining a CE mark, the regulatory clearance requirement for market access, recognized within the European Union.

Contact:

Ralph Schiess, CEO/ Christian Brühlmann, CFO

+41 44 733 40 90

info@proteomedix.com

ProteoMediX AG is a privately held diagnostic company that was founded in March 2010 as a spin-off company from ETH Zurich. ProteoMediX enables personalized medicine by developing non-invasive diagnostic tests to detect and assess the prognosis of cancer, as well as to match patients with safer and more effective therapies. The first products are focusing on prostate cancer, the most frequently diagnosed cancer in men, where neither the detection nor the effective treatment is currently guaranteed. (www.proteomedix.com)

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