

SmartGene

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SmartGene announces CE-IVD labeling of its Service Modules

July 1st, 2015: Zug, Switzerland - SmartGene announces that the SmartGene Service Modules for HIV, HCV, Bacteria, Fungi and HLA have obtained CE-IVD (In Vitro Diagnostic) labeling, following successful notification to Swissmedic, the Swiss Agency for Therapeutic Products. This milestone will facilitate the continued and expanded use of SmartGene's services by certified laboratories, operating in an increasingly regulated environment.

Independently of the evolving regulatory landscape, SmartGene has already applied Computer System Validation (CSV) guidelines for many years, as recommended or requested by regulatory authorities for medical device software. The CE-IVD labeling confirms the assurance of quality and traceability which SmartGene already practices in its software development, maintenance and operational processes. “We believe that adding the CE-IVD label to our service modules is appropriate, to indicate to our customers that our services match their expectations for quality and reliability,” stated Mrs Doris Loutan, Quality Manager at SmartGene. “Our entire team is highly sensitive to the quality aspect in our work and the CE-IVD label is one way of showing it.”

The aforementioned SmartGene Service Modules comply with the Essential Requirements of the IVD Directive 98/79/EC, as stated in our Declaration of Conformity. Our Quality System provides all the technical documentation needed to assess this conformity, addressing software development, updates, risk analysis and post-market surveillance.

About SmartGene

SmartGene GmbH is a privately-held company based in Zug, Switzerland, with subsidiaries in Lausanne, Switzerland and Raleigh, North Carolina. SmartGene provides web-based suites of functionality worldwide to facilitate sequence-based analysis for a variety of clinical, medical research, and veterinary applications. Constant updates to reference data and interpretive algorithms keep SmartGene's customers in step with evolving science and improve the accuracy of sequence interpretations. SmartGene's integrated services increase the speed to result for sequence-based diagnostics and improve work flow in the laboratory. SmartGene's modules address Bacteria, Fungi, HIV, HCV, HSV, MLST, Influenza and HLA typing. Discover more at www.smartgene.com.