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**SmartGene announces certification of compatibility of its Integrated Database Network System<sup>®</sup> (IDNS) platform and service modules under 21 CFR Part 11**

**Zug, Switzerland: 15<sup>th</sup> January, 2019:** SmartGene today announced that its Integrated Database Network System<sup>®</sup> (IDNS) technology platform and service modules have been certified by an independent auditor as compatible with the requirements of Title 21 of the United States Code of Federal Regulations Part 11 (21 CFR Part 11).

21 CFR Part 11 applies to electronic records generated as part of a biomedical product development or manufacture and submitted to the United States Food and Drug Administration (FDA) under requirements of the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Public Health Service Act (PHSA). As the result of an independent audit, SmartGene GmbH has received confirmation that the SmartGene Integrated Database Network System<sup>®</sup> (IDNS) and its associated service modules are compatible with the requirements in 21 CFR Part 11 and that SmartGene has the necessary technical controls in place that will facilitate its customers' certification of their own compliance with the requirements of 21 CFR Part 11.

“Securing this certification of the compatibility of our service platform and modules under 21 CFR Part 11 is an important milestone for SmartGene,” stated Stefan Emler, MD, CEO of SmartGene GmbH. “We see the opportunity to deliver our web services to laboratories providing quality control testing for BioPharmaceutical manufacturing and food processing, and having this certification for our software is critical to expanding our business in these growing market segments.”

This new certification of compatibility under 21 CFR Part 11 is relevant for SmartGene's customers who are operating under Good Manufacturing Practice regulations (GMP), and builds upon SmartGene's established certifications and CE-IVD (*In Vitro* Diagnostic) labeling for the long-standing use of its software in clinical diagnostics applications.

## About SmartGene

SmartGene is a bioinformatics, application service provider (ASP) delivering secure, integrated, software solutions (SaaS) for the analysis, interpretation, and data management of genetic sequences. Customers worldwide use SmartGene's cloud-based modules for multiple applications, including bacterial and fungal identification, microbiome analysis, strain typing, molecular epidemiology of viruses and bacteria, and HIV, HCV, and Influenza genotyping and drug resistance analysis. SmartGene provides specific medical, clinical research, industrial and epidemiological surveillance applications designed for routine workflows from raw data (Sanger, NGS) to comprehensive reports. Frequently updated, quality-controlled, reference databases, interpretative algorithms, specifically parameterized bioinformatics tools, and customized, searchable, sequence databases are integrated within SmartGene's solutions which are CE-IVD labeled and compatible with the requirements of 21 CFR Part 11. Find out more at: [www.smartgene.com](http://www.smartgene.com).