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Dongwoon Anatech's saliva-based glucose monitoring device receives Korea's digital GMP certification

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Developing D-SaLifeÂ® since 2017, the Korean chip designer advances a system that checks blood glucose level from saliva



Dongwoon Anatech Co., a Korean fabless semiconductor company and a pioneer in saliva-based glucose monitoring sensor, has received Digital Medical Device Manufacturing GMP (Good Manufacturing Practice) certification from Korea's Ministry of Food and Drug Safety (MFDS) in connection with D-SaLife®, its saliva-based glucose monitoring system under development.

D-SaLife® is being developed to measure glucose levels from saliva. Dongwoon Anatech began developing the system in 2017 and has spent nearly a decade advancing it, applying the micro-signal sensing and precision control technology it built through two decades of analog semiconductor design.

The Digital Medical Device Manufacturing GMP was newly introduced under Korea's Digital Medical Products Act, which took effect in January 2025. In addition to conventional manufacturing and quality management, it reviews requirements specific to digital products, including software development lifecycle management, cybersecurity and the management of AI algorithms.

In connection with D-SaLife®, Dongwoon Anatech received In Vitro Diagnostic Medical Device GMP certification for clinical-trial products in July 2026 and Digital Medical Device Manufacturing GMP certification in November 2026. Core technologies related to D-SaLife® are patented in Korea, the United States, Europe, China, Japan and India. The company is planning to obtain its regulatory approval from the Korean Ministry of Food and Drug Safety in 2027 and aims to complete registration with the US FDA by 2029.