

Promex Awarded CA FDB Manufacturing License for Class II, Class III Medical Devices; Exhibits Microelectronics Assembly Technology Services at Sensors 2019, IMAPS Advanced SiP

Santa Clara, CA — June 21, 2019 — [Promex](#), a provider of microelectronics assembly technology, is now licensed to manufacture Class II and Class III medical devices by The State of California Food and Drug Branch (FDB) of the Food and Drug Administration (FDA). This license indicates that the FDB has authorized Promex to operate under the rigorous quality guidelines of California's Device Manufacturing Licensing Laws, including compliance with California Health and Safety Code requirements, all applicable state laws, and the federal Good Manufacturing Practice (GMP) and Quality System Regulations (QSR).



Promex Awarded CA FDB Licensed to Manufacturer Class III Medical Devices

Research by [McKinsey & Company](#) found that of the \$380 billion in global sales for medical devices in 2017, poor quality cost device OEMs an estimated \$12 billion, despite an investment by manufacturers of close to \$24 billion in quality procedures and processes. According to Promex Director of Quality and Regulatory Compliance Hassan Sorkhabi, the CA FDB license strengthens Promex's position within the medical device industry as a quality-focused provider of complex engineering and heterogeneous assembly solutions.

“Every change or modification to the design or manufacture of a complex biomedical device creates a new set of variables. We understand the importance of thorough documentation and verified processes and do everything possible to ensure quality for our customers. By incorporating risk management in the Promex quality policy, our organization is adopting a preventive-action approach to most activities performed under our [Quality Management System \(QMS\)](#) – a practice aligned with the latest ISO 13485:2016 and ISO 9001:2015 expectations. As a CA FDB-licensed medical device manufacturing services provider, we use Risk Management and pFMEA after QMS policy implementation for continuous improvement,” Sorkhabi said.

Promex is exhibiting at [Sensors 2019](#) in San Jose, Calif. in Booth 1229 and at [IMAPS Advanced SiP \(System in Package\)](#) in Monterey, Calif. Both events run June 25-27, 2019 and will enable Promex to deliver its message of the importance of quality and the benefits of heterogeneous assembly for the production of sensors, sensor-integrated systems, SiPs, and complex medical devices to a more than 7,000 attendees.

Promex provides design-for-manufacturing services coupled with materials science expertise and broad assembly capabilities for small- to mid-volume onshore production. Located in Silicon Valley since 1975, Promex features Class 100 and Class 1000 cleanrooms. The company is ISO 13485:2016 and ISO 9001:2015 certified, ITAR registered and licensed by the State of California Food and Drug Branch to manufacture Class II and Class III medical devices. More information is available by calling 408-496-0222. <http://www.promex-ind.com>.

Contacts:

Promex: Director of Quality and Regulatory Compliance [Hassan Sorkhabi](#) 408-816-8042
C3PR: [Mar Junge](#) 408-219-0101 or [Paul Neuenschwander](#) 505-440-3090