

Power Supplies

Five major TDK-Lambda Group sites have obtained certifications of ISO13485 quality management system for medical devices

- First acquisition of a standard switching power supply manufacturer in Japan

June 17, 2020

TDK Corporation is pleased to announce that its subsidiary company, TDK-Lambda Corporation (President: Hiroyuki Yashiro, hereafter TDK-Lambda) Nagaoka Technical Center (Nagaoka City, Niigata Prefecture), received a certification of ISO13485: 2016^{*1} Medical devices quality management systems for its quality management system. It is the first among the standard switching power supply manufacturers in Japan.

Scope of Registration:

The Design/Development, Manufacturing and Servicing Activities (Analysis, Repair and Overhaul for Field Returns) of Components (Switching Power Supply) for Active Medical Devices.

TDK-Lambda has been focusing on the medical device market and actively working to acquire ISO13485 certification throughout the Group. Now, TDK-Lambda's major development design and production sites in Japan, the United Kingdom, the United States of America, China, and Malaysia have been certified. This will leverage the Group's capability to provide products and services that can be adopted with higher confidence in the global medical device market.

Terms

^{*1} ISO13485

ISO 13485, Medical devices – Quality management systems – Requirements for regulatory purposes, is an internationally recognized standard for quality management systems for medical devices. Adopting ISO 13485 provides a practical foundation for manufacturers to address the Medical Device Directives, regulations, and responsibilities as well as demonstrating a commitment to the safety and quality of medical devices.

About TDK Corporation

TDK Corporation is a world leader in electronic solutions for the smart society based in Tokyo, Japan. Built on a foundation of material sciences mastery, TDK welcomes societal transformation by resolutely remaining at the forefront of technological evolution and deliberately “Attracting Tomorrow.” It was established in 1935 to commercialize ferrite, a key material in electronic and magnetic products. TDK’s comprehensive, innovation-driven portfolio features passive components such as ceramic, aluminum electrolytic and film capacitors, as well as magnetics, high-frequency, and piezo and protection devices. The product spectrum also includes sensors and sensor systems such as temperature and pressure, magnetic, and MEMS sensors. In addition, TDK provides power supplies and energy devices, magnetic heads and more. These products are marketed under the product brands TDK, EPCOS, InvenSense, Micronas, Tronics and TDK-Lambda. TDK focuses on demanding markets in automotive, industrial and consumer electronics, and information and communication technology. The company has a network of design and manufacturing locations and sales offices in Asia, Europe, and in North and South America. In fiscal 2020, TDK posted total sales of USD 12.5 billion and employed about 107,000 people worldwide.

About TDK-Lambda Corporation

TDK-Lambda Corporation is a trusted, innovative leader and global supplier of highly reliable power conversion products for industrial and medical equipment worldwide.

TDK-Lambda Corporation is aligned for fast responses to any customer need with R&D, manufacturing, sales and service locations in five key geographic regions, namely Japan, EMEA, Americas, China and ASEAN.

For more details, please pay a visit to: www.jp.lambda.tdk.com/en/

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