

eSOL's RTOS Product Development Process Certified under IEC 62304 Safety Standard for Medical Devices

Helping Reduce Development Costs for Medical Device Subject to Strict Safety Criteria and Regulation



Tokyo, Japan. March 13, 2017 – eSOL, a leading developer of real-time embedded software solutions, today announced that the development processes for its real-time OS products have been certified by SGS-TÜV Saar GmbH of Germany, an international certification agency, as complying with the IEC 62304:2006 (medical device software – software life cycle processes) standard for the development and maintenance of medical device software. In conjunction, eSOL has also commenced delivery of the eT-Kernel real-time operating system (RTOS), which was developed using a process that complied with the requirements of IEC 62304. In doing so, eSOL is helping reduce the time and cost associated with the development of medical devices that demand high levels of safety and reliability, and for which strict manufacturing and sales certifications/applications must be obtained in markets such as the United States and Europe as well as Japan.

IEC 62304 is an international standard published in May 2006 that specifies a framework for the life cycle processes of medical device software. It stipulates the requirements for software development and maintenance to improve the safety of this software. The standard satisfies requirements specified in European directives such as the Medical Device Directive (MDD), also known as 93/42/EEC, and In Vitro Diagnostic Devices Directive (IVDD). IEC 62304 is also recognized by the US Food and Drug Administration (FDA). In Japan, IEC 62304:2006 has been adopted as “JIS 2304:2012 (medical device software – software life cycle processes)” and is the standard for satisfying the requirements of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices (the Pharmaceutical and Medical Device Law) amended in

2014. Accordingly, an essential requirement for the manufacture and sale of medical devices in different countries is that the device software be developed using processes stipulated by IEC 62304.

The eT-Kernel RTOS is used in a wide range of applications, including automotive devices, industrial equipment, satellites, and consumer appliances. The eT-Kernel Compact basic profile was the first Japanese OS to obtain the highest product certification safety levels (ASIL D and SIL 4) under the ISO 26262 and IEC 61508 functional safety standards for automotive and industrial equipment respectively. For eT-Kernel users developing systems that demand high levels of safety, eSOL also supplies the eT-Kernel Safety Package that bundles safety manuals, safety reports, and other documents. Moreover, the eBinder integrated development environment that is tightly integrated with eT-Kernel has been developed in a process to satisfy the requirements of ISO 26262 and IEC 61508. eT-Kernel is provided as a software platform that integrates with a range of middleware and professional services as well as eBinder.

“eSOL continually strives to improve the quality and reliability of our software and services,” said Nobuyuki Ueyama, Executive Vice President, eSOL Co., Ltd.. “We have used a quality management system (QMS) for embedded software development that we established based on ISO9001:2008. Now, we have obtained certification that our QMS for RTOS related products complies with the requirements of IEC 62304. By supplying RTOSs for medical device software as well as related services, we provide powerful support for medical device developers seeking to comply with IEC 62304, an essential requirement for satisfying the stringent regulations and safety standards of different countries.”

About eSOL

Founded in 1975, eSOL is a leading developer of real-time embedded software solutions that seeks to create a rich IoT society using its innovative computer technologies. eSOL’s software platform products and professional services, centered around its real-time operating system technology, are used worldwide in every field, starting with automotive systems, which conform to the most stringent quality standards, and including industrial equipment, satellites, and digital consumer electronics. In addition to the research and development of its own leading-edge products, and joint research with major manufacturers and universities, eSOL is actively engaged in AUTOSAR and Multi-Many-Core technology standardization activities. For more information, please visit <http://www.esol.com/>