ROCHESTER ELECTRONICS COMMUNICATIONS

A Rochester Electronics White Paper

RoHS Compliancy in the Medical Equipment Supply Chain by 2014

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Executive Summary

The Restriction of Hazardous Substances (RoHS) directive has been an ongoing initiative in many industries across the electronics' supply chain since the concept surfaced in the European Union in 2006. The EU's 2006 RoHS directive banned the use of six substances—lead (Pb), mercury (Hg), hexavalent chromium (Cr (VI)), cadmium (Cd), polybrominated biphenyl flame retardants (PBB), and polybrominated biphenyl ether flame retardants (PBDE)—in eight categories of electrical/electronic equipment. The mission of the ROHS project is to remove hazardous materials from electronic devices in order to facilitate the elimination of hazardous waste effects on the environment. In December 2013, the RoHS exemption that was put in place for the medical industry will expire, and companies will be forced to comply with current regulations. These regulations will prohibit any leaded and non-RoHS materials from medical equipment, which, will cause a challenge for the medical industry as they figure out what is available for their applications. As a result of long product life-cycles, they may discover that the devices have since gone obsolete, or were never available in a RoHS package, which could ultimately lead to costly redesigns. With that in mind, medical companies are finding themselves scrambling to meet regulations with their manufacturers, and keep their businesses compliant.

The leaded-to-lead-free & RoHS Compliant conversion

Regardless of their current RoHS exemption, both medical manufacturers and companies across the industry have seen a noticeable increase in requests for documentation relating to environmentally preferred products (EPP). Leading companies are losing out on significant opportunities and bids due to their inability to show their customers required EPP documentation, which discloses material usage and regulatory compliance certification. The increase in these types of requests stemmed from the RoHS directive initiative that had been employed across a number of industries. Unfortunately, moving from one requirement to the next is not an easy task. Companies within the medical industry have put pressure on their suppliers to execute the required processes needed to comply with RoHS constraints, but continue to hit obstacles along the way. Medical manufacturers and existing companies have experienced mergers and acquisitions which have temporarily fragmented productivity, and while the medical industry faces the expiry of their exemption, they have to simultaneously plan for the next revision of RoHS (and most likely those of REACH) guidelines that will include additional hazardous materials restrictions.

Imminent additional compliances known as the Dodd-Frank Wall Street Reform and Consumer Protection Act include a section specific to the procurement of certain conflict minerals from the Republic of the Congo (DRC). The minerals that are up for discussion are tantalum, tin, tungsten, and gold. These minerals are the source of increased amount of violence and criminal activity within the DRC region, and continuing to procure these only adds fuel to the fire. These minerals are used commonly within the electronics industry and because the Act is fairly new, stipulations and consequences are still being worked out.

The last cause for concern revolves around the substance restrictions, and the overall effect it could have on the functionality of medical system applications. For example, lead has proven to be an effective element in solder because of its ability to restrict the growth of "tin whiskers." RoHS devices using tin as a replacement terminal

finish for lead can become highly susceptible to growing "tin whiskers." As a result, any whiskers that form can short the device and cause the device to fail.

What it means to be RoHS Compliant from a supplier point-of-view

From a competitive standpoint, remaining compliant can save a company a lot of time and hassle, which can ultimately maximize efficiency throughout the supply chain. In addition to increased efficiencies, compliance benefits also include reduction in administration costs and total costs, accelerated time to market, a decrease in supply chain risks (receiving non-RoHS devices), and an overall improvement in supplier performance and customer collaboration. It is vital that medical companies establish relationships with compliant manufacturers and authorized distributors to help alleviate any potential threats that would close down a smooth-running production line and overall operation. While these points all remain true, it is also important to realize that the ROHS Compliant Initiative will restrict companies from shipping to Europe for as long as they remain non-compliant. Threats of non-RoHS compliant devices linger within the supply chain, along with substandard RoHS devices that are not from the original manufacture.

Relying on an authorized source during the transition from exemption-to-RoHS will help medical companies get their customers the devices and materials they need as soon as possible, with the confidence that the devices are in-fact compliant, and functioning properly. There are life-critical applications in the medical industry, and it is essential that the procurement of compliant devices is taken seriously.

How Rochester can help with RoHS and non-RoHS component requirements

Based on the new requirements, medical OEMs may find themselves in a situation where specific devices have gone obsolete, and as a result, could end up with costly re-design charges. Rochester Electronics and other leading companies in the electronics industry are trust-worthy, authorized sources of semiconductors and have been for decades, supporting industries such as aerospace, defense, telecommunications, as well as medical. With billions of factory-direct devices in stock, including those which are RoHS compliant, Rochester has been able to provide the devices needed as they are needed, for more than 30 years.

In addition, Rochester Electronics' ever expanding manufacturing services include the continued manufacture of finished devices from billions of original OCM die, carefully stored in the largest on-site die bank in the world. Rochester has full authorization from the original component manufacturers to build the necessary component that would allow for continued, uninterrupted production at equipment manufacturers. Through the acquisition of OCM intellectual property, Rochester Electronics has the ability to package product in its required package type, even if that package was never offered in the past. To the medical industry's imminent requirements, this includes RoHS and lead-free packaging as well.

RoHS Compliancy in the Medical Equipment Supply Chain by 2014

Conclusion

Rochester Electronics has contractual agreements with more than 60 manufacturers including Texas Instruments, Intel, AMD, Analog Devices, and Fairchild. With these contracts in place, it allows Rochester Electronics the ability to manufacture devices in the required package type, whether leaded, or RoHS compliant. All components are 100% manufacturer traceable and certified, with a product offering that includes more than 300,000 Rochester-manufactured device types, from commercial to space-level. In addition, as a fully authorized source, Rochester Electronics alleviates any concern of counterfeit devices. As the medical industry transitions to RoHS compliancy, there is a growing concern that unauthorized devices may be marked as RoHS compliant when they are not manufactured as such. Rochester Electronics can help company's decrease the amount of uncertainty they will face with the conversion from leaded to RoHS. By offering complete solutions for both leaded and lead-free components, the original equipment manufacturers of medical systems are assured of completed compliance, uninterrupted supply, and guaranteed authentic product.

For more information on the RoHS policies and trends, go to *http://www.cocir.org/* for information on how the counterfeit components being sold on the open/gray market can affect you, go to www.AuthorizedDirectory.com .

About Rochester Electronics, LLC

Rochester Electronics is the world's most comprehensive solution for mature and end-of-life semiconductors. Authorized by more than 60 leading semiconductor manufacturers, Rochester acquires all remaining finished devices, wafer/die, and available intellectual property in order to manufacture the exact same device and provide a reliable, continuing source of semiconductors used in critical systems worldwide — in any quantity and for as long as needed. All components are 100% manufacturer traceable and certified. Rochester's product offering includes 300,000+ Rochester-manufactured device types, from commercial to space-level; complete, authorized device re-creation, as well as billions of die and finished devices, in stock and ready to ship. Rochester is certified to ISO-9001:2008 and QML MIL-PRF-38535, as well as AS9120. Rochester is privately held. Sales offices are located throughout the United States, Europe, and Asia. Visit www.rocelec.com to check inventory and read about our line-up of capabilities.