

Environmental compliance for medical device products

The total solution for environmental compliance for the medical device and diagnostics industry

Benefits

- Support environmental stewardship initiatives and green business processes
- Reduce the risk of building products that can't be sold in key markets
- Demonstrate due diligence by building a compliance audit trail
- Reduce environmental data collection cycle times and cost
- Reduce analysis and reporting cycle times and cost
- Provide engineers with up-to-date compliance status of all components
- Enable green design
- Minimize the cost of excess and obsolete inventory due to noncompliance
- Keep pace with new and constantly changing environmental regulations and exemptions
- Easily integrate with your existing systems

Features

- Automatic generation and tracking of compliance and material content reports
- Supplier portal to facilitate information gathering and ensure partner compliance

Summary

Teamcenter® software's complete solution for end-to-end management of environmental compliance and material content information provides medical device and diagnostics OEMs with a flexible and easy-to-deploy toolset to meet the industry's strict environmental compliance requirements.



Teamcenter plays an important and growing role in helping companies develop "green," environmentally friendly products. Teamcenter environmental compliance solution enables medical device and diagnostics OEMs to understand and control the material makeup of their products, and to comply with environmental regulations that seek to limit the use of hazardous substances in products. Teamcenter reduces the costs associated with collecting and managing the vast amount of environmental data required to establish and document the compliance of complex products down to the substance level.

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Features *continued*

- Material content management for parts and products
- Compliance validation against multiple regulatory, internal or customer standards
 - Easily configurable XML templates
 - Ability to manage regulatory exemptions and timeframes
 - Support for multiple compliance status levels
- Material content and compliance aggregation across multi-sourced components (patent pending)
- Data exchange support for industry standard protocols:
 - IPC-1752 – Material Content Declaration
 - RosettaNet 2A10, 2A13 and 2A15 PIPs
- Integration of compliance information into standard business processes:
 - Change management
 - CAD Integration
 - Supplier qualification
 - Part qualification
- Ability to determine compliance status at any point during the product's lifecycle
- Ability to integrate into existing supply chain, design and manufacturing systems such as:
 - ERP (Oracle, SAP and others)
 - Item master (i2 eXplore and others)

Business context

It is estimated that by 2010, more than 75 percent of all electronic products will be sold in countries with legislations similar to REACH, RoHS and WEEE. For example most of South Korea's high tech and electronics companies recently adopted a voluntary compliance program. Japan, currently the world's largest consumer of lead-free solder paste, has had voluntary lead-free initiatives in place for many years. In the USA, individual states (California, Maine and others) have already enacted laws that require goods sold in those states to comply with environmental requirements.

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is a regulation of the European Union that regulates chemical substances which are manufactured or imported into member states. REACH will also restrict an estimated 1,500-3,000 substances of very high concern (SVHCs) currently found in products. REACH will broadly impact industries throughout the world, including medical devices.

Restriction of hazardous substances (RoHS) Directive 2002/95/EC is a directive of the European Parliament & Council banning from the EU market electrical and electronic equipment (including but not limited to electrical and electronic tools, consumer goods, household appliances) containing more than set levels of specific substances (such as lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers).

China RoHS refers to the "Management Methods for Controlling Pollution Caused by Electronic Information Products Regulation" directive published by China's Ministry of Information Industry (MII) on March 1, 2006. It is similar to EU RoHS but it has a wider scope and different requirements; China RoHS law affects the entire supply chain.

Commercial Part Summary		With Physical Content Disclosure	Without Physical Content Disclosure
Total Parts	0	0	0
RoHS	0	0	0
Parts with Exemptions	0	0	0
Material Fail	0	0	0
Fail	0	0	0
Success	0	0	0

Korea RoHS or "The Act for Resource Recycling of Electrical/ Electronic Products and Automobiles" is a RoHS/ WEEE/ELV-like legislation enacted on March 30, 2006. The scope is very broad and inclusive and includes aspects of EU RoHS, WEEE and ELV. The act covers all electrical and electronic products, as well as automobiles.

The Waste Electrical and Electronic Equipment (WEEE) Directive is an EU directive that requires producers to provide recovery and recycling programs for the processing of electrical and electronic equipment.

Developing environmentally compliant products is a must for any medical device OEM that competes in the global marketplace. Medical devices were initially excluded from EU RoHS but subsequent regulations expanded the industry scope. The supply chain is unquestionably moving toward compliant materials, phasing out and replacing current components and materials with new green ones. Therefore, medical device OEMs can not afford to wait for the changes to be forced upon them by their supply chain; rather they must take a proactive approach and initiate a conversion of their products.

Noncompliance costs can range from fines to more severe penalties, including being prevented from competing in key markets. Lack of visibility to compliance information can also lead to increased excess and obsolete cost and excessive product redesign costs. With a myriad of current and future mandates such as EuP (Energy-using products) on the horizon, companies have to think strategically about the environment and realize that sustainable business practices are linked to environmental stewardship and “green” business practices.

Key capabilities

Teamcenter off-the-shelf environmental compliance solution is flexible, affordable and easy to deploy. Ideally suited for the

medical devices industry, Teamcenter enables manufacturers to meet current regulations while establishing an enterprise-wide framework for staying ahead of ever-evolving requirements. Teamcenter maximizes the visibility of compliance information in all stages of the product lifecycle and thus minimizes the risks and costs associated with non-compliance.

Teamcenter offers a complete set of functionality for analyzing and tracking compliance at the substance, material, part and product levels.



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