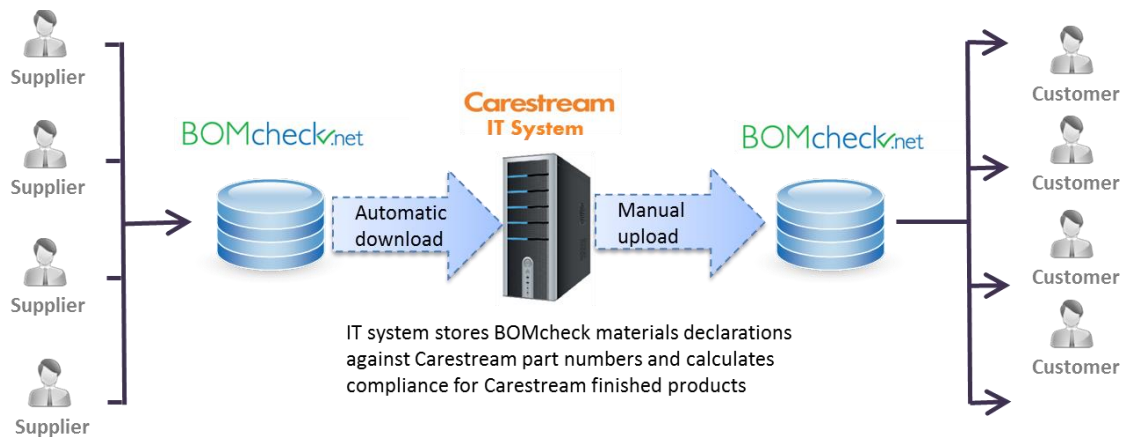# Carestream

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Carestream Health achieving RoHS2 Compliance for Medical Devices with EN 50581 and BOMcheck

Standardised materials declarations meet EN 50581 quality requirements

IT system stores BOMcheck materials declarations against Carestream part numbers and calculates compliance for Carestream finished products

Compliance challenge

Carestream Health, Inc. is a worldwide provider of medical and dental imaging systems and healthcare IT solutions; X-ray film and digital X-ray systems for non-destructive testing; and advanced materials for the precision films and electronics markets. Formerly a division of Eastman Kodak, Carestream serves a diversified customer base in approximately 170 countries with annual revenues in 2013 of US$2.4 billion.

The new EU RoHS2 Directive requires certain medical devices to comply with stringent restrictions on lead, cadmium, chromium, mercury and polybrominated flame retardants in every material in every component by July 2014. The metals can become toxic and leach into groundwater when disposed in landfill or become hazardous ash when incinerated. All medical equipment products at Carestream are affected, comprising 50,000 individual components procured as sub-assemblies and hardware items.

"This was a daunting task requiring a massive amount of data collection from our suppliers around the world. The BOMcheck web database system was absolutely the correct choice for us" said Dale Parks, Carestream Worldwide RoHS Program Manager.

EN 50581 Risk Management Standard

The EN 5081 European Standard was published in September 2012 and officially endorsed by the European Commission in December 2012, as an approved method for compliance with RoHS2 Technical Documentation requirements. The standard provides a risk management system which enables manufacturers to rely on objective evidence of RoHS2 compliance provided by their suppliers. EU RoHS regulatory authorities expect companies to adopt the EN 50581 standard or provide evidence that their compliance approach provides equivalent quality levels.

Carestream established a worldwide team to implement the EN 50581 standard at manufacturing sites in Rochester, Long Island, Israel, Paris and Shanghai with centralised program management in Rochester. The company introduced several new processes including; new supplier selection criteria, RoHS audits of selected suppliers, x-ray fluorescence screening at manufacturing sites, contractual requirements for suppliers to create industry standard IPC 1752A materials declarations in BOMcheck and attach test reports as required, automatic download of IPC 1752A materials declarations from BOMcheck to the Carestream Product IT system and BOM roll-up capability to calculate compliance for Carestream finished products.

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Web database collects supplier declarations

Carestream applied the EN 50581 risk assessment process to identify sub-assemblies and hardware items that have no risk of containing RoHS substances, or are exempt from RoHS requirements. Carestream purchase order terms and conditions mandate that priority suppliers that provide the remaining sub-assemblies and hardware items must provide RoHS compliant materials and parts, join www.bomcheck.net (if they are not already a member) and use the BOMcheck Supplier Account tools to create industry standard IPC 1752A materials declarations and attach test reports as required.

Three sites located in Paris, Rochester and Shanghai use the Super User Account tools to invite suppliers who are not already members to join BOMcheck, and to send requests to suppliers to make declarations in BOMcheck for Carestream parts.

By May 2014, Carestream is on track to achieve 100% RoHS2 compliance for all affected medical equipment in advance of the July 2014 deadline. 74% of priority suppliers have made 6,360 declarations in BOMcheck for sub-assemblies and hardware items, with the remaining items being tested. In the process, Carestream has eliminated over 900kg of RoHS hazardous substances from its medical equipment.

Automatic download to Carestream IT system

BOMcheck provides a fully documented API interface and example programming code which Carestream Health implemented to provide a web connection between their IT system and BOMcheck. The Carestream IT system can send requests to BOMcheck for lists of supplier part numbers and BOMcheck downloads the supplier materials declarations in industry standard IPC 1752A format into a dedicated product folder at Carestream ready for loading into the IT system.

The IT system stores the BOMcheck IPC 1752A materials declarations against Carestream part numbers and has capability to roll up the data for the BOM parts list to calculate compliance for the Carestream finished product. Carestream then manually uploads a RoHS2 materials declaration for the finished product to BOMcheck for Carestream customers to access.

"We are proud of our commitment to environmental health and safety and follow a set of "ē·co·pride" principles where:
ē represents the environmental and the employee health and safety considerations,
co represents the compliance and the cost expectations, and
pride represents how Carestream embraces, integrates and demonstrates its obligations."

Dale Parks, Director-Worldwide Equipment Compliance

About BOMcheck

BOMcheck is an industry collaboration led by Philips, Siemens, GE, Osram, Sony Mobile, Schneider Electric, Toshiba, Agfa, Texas Instruments, Carestream Health and TE Connectivity to share one web database system to manage supply chain compliance. The web system is easy to use and enables suppliers to create and share standardised high quality materials declarations with their manufacturer customers. BOMcheck is highlighted in several corporate videos and is currently used by over 800 manufacturers to gather materials declarations from over 7,000 suppliers worldwide for more than 2.5 million parts.

BOMcheck was awarded 2014, 2015, 2016 and 2017 Top Product of the Year in the Environmental Leader Product & Project Awards. The Environmental Leader Awards recognize excellence in products and services that provide companies with environmental benefits.

Further information is available at www.bomcheck.net and by contacting support@bomcheck.net.