



Trinseo is a global plastics manufacturer relied on by many of the premier OEMs in the Medical Device industry. Large and global in our infrastructure yet lean and agile in our service model, we collaborate intimately with customers, developing custom material solutions to meet complex challenges. Our brands and resins are recognized globally and include: CALIBRE™ and CALIBRE™ MEGARAD™ Polycarbonate Resins, EMERGE™ Advanced Resins, MAGNUM™ ABS Resins and STYRON™ Polystyrene Resins.

For more information on products, innovations, expertise, and other services available from Trinseo, contact your Trinseo representative or CIG@trinseo.com or visit us at www.trinseo.com

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ISO 13485: How to Lower Risk and Improve Speed to Market

What is ISO 13485?

ISO 13485 is a designation of the International Organization for Standardization specifying requirements for a quality management system that supports medical devices.

ISO 13485 challenges companies to focus on Risk Management and Process Validation and determine ways to improve performance by:

- **Evaluating risk factors such as inventory levels, supply chain and facilities**
- **Implementing steps to analyze and measure processes rather than only having processes in place**

Why it's important

Simply put, ISO 13485 helps companies lower risk and improve speed to market. Manufacturers align to it because it provides a process for consistent, predictable and sustainable operations—while reflecting and supporting global regulatory standards for medical devices. This means manufacturers can be more confident that their finished applications will be compliant with industry standards.



Who gets certified?

ISO 13485 can apply to any company in the supply chain. Trinseo earned ISO 13485: 2016 certification in October 2016 for "Plastics Development and Manufacturing to Support our Medical Device Business." Our certification applies to Trinseo facilities and functions that manufacture and produce medical compounds, as well as the global functions — Technical Service & Development, Research & Development, Quality, Sales and Human Resources.

What Trinseo certification means to you

- Trinseo is committed to ensuring the plastics going into your medical devices adhere to industry and global harmonization objectives for quality and safety
- Trinseo has a deep understanding of the regulatory landscape in the medical device industry, as well as expectations of industry OEMs
- Our risk management approach to plastics development and manufacturing stresses identifying, controlling and eliminating risk
- We're focused on producing quality products consistently and sustainability and being your reliable source for plastics for your critical medical devices
- Our efficient manufacturing and collaboration with your supply chain ensures optimal application production with the potential of increasing your speed to market
- With ISO 13485, Trinseo speaks your language



Trinseo's ISO 13485 certification for Plastics Development and Manufacturing means we are a true partner to our medical device customers. With our business approach and thought processes completely aligned in discipline and commitment, Trinseo is your ally in ensuring reliable quality output and reducing the risk of non-compliance.