



## ISO 13485:2016

助您降低风险，加快产品推出市场

Helping You Reduce Risk and Improve Speed to Market

获得 ISO 13485 认证，充分证明盛禧奥是塑料开发和医疗设备制造的理想合作伙伴。我们的商业模式和思维能结合业界的需求，同时反映出我们对客户的承诺。因此，盛禧奥是您的盟友，助您的产品达致高质量，并有效降低不合规风险。

Trinseo's ISO 13485 certification for plastics development and manufacturing demonstrates we are a true partner to our medical device customers. With our business approach and thought processes aligned in both discipline and commitment, Trinseo is your ally in ensuring reliable quality output and reduced risk of non-compliance.

# 什么是 ISO 13485?

## What is ISO 13485?

ISO 13485 是国际标准化组织认可的一项质量管理认证，以证明组织在提供医疗设备及相关服务时，能一贯地满足适用的法规要求、临床疗效和安全期望。

ISO 13485 要求企业对风险管理和流程验证有全面的关注。它通过以下各项来确定表现得到持续的改善和关注：

- 评估库存、供应链和设施等方面的风险因素。
- 采取一定的步骤来分析和衡量流程而不仅是制定流程。

## 它为什么如此重要?

### Why it's important?

概括来说，ISO 13485 可帮助公司降低风险，并有助产品加快推出市场。制造商竭力通过此认证，因为它能提供一个一致、可预测和可持续的运营流程，同时符合和支持医疗设备领域的全球法规标准。通过这模式，制造商可确保他们的制成品符合行业标准。

## 哪些领域获得认证?

### Which fields are certified?

盛禧奥于 2016 年 10 月获得 ISO 13485 认证，实现‘为支持医疗设备行业而进行塑料开发和制造’的目标。该认证适用于盛禧奥制造和生产医疗化合物的相关设施和职能部门，包括技术服务、研发、质量、销售和人力资源等运营部门。

## 它对您来说意味着什么?

### What it means for you?

- 盛禧奥致力确保您用于医疗设备中的塑料，确切符合国际认可质量和安全标准。
- 盛禧奥全面了解医疗设备行业的法规监管和 OEM 的期望。
- 对塑料开发和制造，我们管理风险的方法是识别、控制和消除风险。
- 我们致力生产品质一致，并兼备可持续性的高质素产品；同时为您的关键医疗设备保留可靠的塑料来源纪录。
- 我们的高效生产程序与您的供应链保持合作，确保最佳生产的同时，有助您加快产品上市的速度。
- 我们理解并积极配合您的质量标准，确保与你的要求一致，令你信赖。

ISO 13485 is a quality management certification by the International Organization for Standardization that recognizes an organization's abilities to provide medical devices and related services that consistently meet applicable regulatory requirements, as well as effectiveness and safety expectations.


ISO 13485 challenges companies to commit to a thorough focus on risk management and process validation. It determines ways to improve performance through:

- Evaluating risk factors in areas such as inventory, supply chain, and facilities.
- Implementing steps to analyze and measure processes rather than simply having processes in place.

Put simply, ISO 13485 helps companies reduce their risk and improve speed to market. Manufacturers pursue it because it provides a process for consistent, predictable and sustainable operations, while meeting and supporting global regulatory standards for medical devices. Through its model, manufacturers can be confident their finished applications are compliant with industry standards.

Trinseo earned ISO 13485 certification in October 2016 for 'Plastics Development and Manufacturing to Support Medical Device Business.' The certification applies to Trinseo's facilities and functions that manufacture and produce medical compounds, as well as our Technical Service & Development, Research & Development, Quality, Sales, and Human Resources operations.

- Trinseo is committed to ensuring the plastics in your medical devices adhere to internationally accepted standards of quality and safety.
- Trinseo has a comprehensive understanding of the regulatory landscape in the medical device industry, and expectations of industry OEMs.
- Our risk management approach to plastics development and manufacturing emphasizes the identification, control and elimination of risk.
- We are focused on producing quality products consistently and sustainably, while remaining your reliable plastics source for your critical medical devices.
- Our efficient manufacturing procedures and collaborations with your supply chain ensure optimal production while potentially increasing your speed to market.
- We match and understand your standards of quality, assuring trust and consistency.



盛禧奥是一家全球塑料制造商，医疗设备市场的许多领先 OEM 都采用其产品。我们实力雄厚，具备全球化的生产及研发设施，但我们仍保持着精简和灵活的服务模式。我们与客户紧密合作，开发出能迎合复杂材料挑战的高效能解决方案。我们广受全球认可的知名树脂品牌包括 CALIBRE™ 和 CALIBRE™ MEGARAD™ 聚碳酸酯树脂、EMERGE™ 高级树脂、MAGNUM™ ABS 树脂和 STYRON™ 聚苯乙烯树脂。

Trinseo is a global plastics manufacturer relied upon by many leading OEMs in the medical device industry. Substantial and global in our infrastructure, yet lean and agile in our service model, we collaborate intimately with our customers, developing effectual material solutions that meet complex challenges. Our globally recognized brands and resins include CALIBRE™ and CALIBRE™ MEGARAD™ Polycarbonate Resins, EMERGE™ Advanced Resins, MAGNUM™ ABS Resins, and STYRON™ Polystyrene Resins.



如需了解盛禧奥提供的产品、创新、专业技术和其他服务的详细资料，请浏览本公司网站：[www.trinseo.com](http://www.trinseo.com)，或按以下信息联络我们。

For more information on products, innovations, expertise, and other services available from Trinseo, visit [www.trinseo.com](http://www.trinseo.com), or contact us as indicated below.

盛禧奥 (Trinseo) 和其附属公司在文件印刷方面均秉承责任关怀® 和可持续发展的原则。为保护环境，只印刷少量资料，并尽可能使用含有可回收 / 再生纤维的纸张，并尽可能使 100% 豆制品油墨印制。

The principles of Responsible Care® and Sustainable Development influence the production of printed literature for Trinseo S.A. and its affiliated companies. As a contribution towards the protection of our environments, Trinseo's printed literature is produced in small quantities and on paper containing recovered/post-consumer fiber and using 100 percent soy-based ink whenever possible.

#### 产品监管 PRODUCT STEWARDSHIP

盛禧奥及其附属公司拥有一个基本原则，就是关怀所有制造、分销和使用其产品的人员以及我们生活的环境。这是我们的产品监管原则的基础，我们根据监管原则评估我们产品的安全、卫生和对环境的影响，然后采取适当措施来保护我们的员工、公共卫生和环境。我们的产品监管的成功取决于与盛禧奥产品有关的每个人 - 从每件产品的构思和研究开始到制造、使用、销售、处置以至循环再生。

Trinseo and its affiliated companies have a fundamental concern for all who make, distribute, and use their products and for the environment in which we live. This concern is the basis for our Product Stewardship philosophy by which we assess the safety, health, and environmental information on our products so that appropriate steps may be taken to protect employee and public health and our environment. The success of our product stewardship program rests with each and every individual involved with Trinseo products - from the initial concept and research, to manufacture, use, sale, disposal, and recycle of each product.

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客户有责任从健康和环境保护出发，全面检查其生产过程以及对盛禧奥产品的应用，以保证盛禧奥的产品不会被以其不适合的方式使用。盛禧奥人员将回答您的问题并提供合理的技术支持。客户在使用盛禧奥产品之前，应该查阅盛禧奥的产品文献，包括安全数据表。目前，安全数据表可从盛禧奥获得。

Customers are responsible for reviewing their manufacturing processes and their applications of Trinseo products from the standpoint of human health and environmental quality to ensure that Trinseo products are not used in ways for which they are not suitable. Trinseo personnel are available to answer questions and to provide reasonable technical support. Trinseo product literature, including safety data sheets, should be consulted prior to the use of Trinseo products. Current safety data sheets are available from Trinseo.

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盛禧奥要求客户在考虑将盛禧奥产品用于医疗用途之前先查阅盛禧奥的医疗应用政策，网址为：<http://www.trinseo.com/medical.htm>。该政策规定的各种限制和免责声明都被列入该政策作为参考。

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