TRINSEO MEDICAL APPLICATION POLICY

Trinseo produces medical grade resins under stringent quality guidelines and controlled conditions. We strive to understand our customers' needs and expectations regarding patient safety, reliability, and compliance with regulatory requirements, and to provide biocompatible resins according to ISO 10993 standards. Additionally, Trinseo medical grade resins are subject to management of change and "formula lock" that involve notifying customers of an upcoming change followed by locking that formula for an extended period of time.

Based on Trinseo's interest in collaborating with its customers, Trinseo has developed an internal process for reviewing customer requests for use of ISO 10993-certified materials in certain medical applications. Through this review process, we determine whether or not Trinseo will support the use of Trinseo materials in the proposed medical application based on *1.) Device Category, 2.) Type of Body Contact, and 3.) Duration of Body Contact* utilizing the ISO 10933-1:2009 guidelines, *Biological Evaluation of Medical Devices Part 1: Evaluation & Testing.*

As part of the Trinseo review process, Trinseo will consider the proposed medical applications based on the following guidelines:

Category A (Limited Exposure): Trinseo may support the use of Trinseo materials in medical applications involving transient or limited contact with internal human body fluids or tissues, where "transient" means less than 24 hours.

Category B (Prolonged Exposure): Trinseo may support the use of Trinseo materials in medical applications involving contact with internal human body fluids or tissues for up to 29 days.

Category C ("Permanent" Contact): Trinseo may support the use of Trinseo materials in medical applications involving contact with internal human body fluids or tissues for greater than 29 days.

However, in no event will Trinseo support the use of Trinseo materials in medical applications classified as implant devices or birth control devices, defined as applications designed specifically to promote or interfere with human reproduction.

If customers, distributors or resellers fail to comply with this Policy, and Trinseo becomes aware of said situation, then Trinseo business units shall take steps required to immediately preclude further sales to that end use.

In all of the categories above, Trinseo will exercise its business judgment and conduct appropriate assessments when forming supplier/ customer relationships and supplying materials. Trinseo has not designed or tested its products with respect to all possible uses in medical applications. While Trinseo will commit to meet product specifications and quality standards agreed with the customer, it is the responsibility of the medical device or pharmaceutical manufacturer to determine the suitability of the parts and raw materials, including Trinseo products, used in final products to ensure safe, suitable, lawful and technical compliance for the intended end use.