



# STANDARD TERMS AND CONDITIONS OF SALE APPLICABLE TO PURCHASES OF TOTALENERGIES

*In addition to Bamberger Amco Polymers' Standard Terms and Conditions, the following TotalEnergies terms are applicable to your purchase of TotalEnergies branded resin:*

1. Total Petrochemicals & Refining usa, inc. ("manufacturer" or "TotalEnergies") warrants that the product shall meet manufacturer's specification for this product. Manufacturer makes no other representations or warranties of any kind, express or implied, including any implied warranties of merchantability or fitness for a particular purpose regarding product. Manufacturer shall not be liable for any special, indirect, consequential, or punitive damages, including but not limited to, loss of anticipated profits, loss of use, loss of revenue, downtime costs, loss of business opportunity, and cost or capital. Manufacturer's liability and your exclusive remedy for claims is expressly limited, at manufacturer's option, to replacement of nonconforming product or a credit or reimbursement not to exceed the amount paid to manufacturer with respect to the products for which the claim is made.
2. For any claim relating to the quantity or specifications of the Products for any reason, you (the purchaser) must provide notice, with supporting documentation, to Distributor (Bamberger Amco Polymers) within thirty (30) days after delivery of Product that is the subject of the claim, or such claim shall be deemed to be barred and to have been waived. Distributor's sole and entire liability and your sole and exclusive remedy for any such claims are limited, at Distributor's option, to replacement of nonconforming Product or a credit or reimbursement not to exceed the amount paid to Distributor with respect to the Product for which the claim is made.

3. **THESE TERMS APPLY TO YOUR PURCHASE OF TOTALENERGIES PRODUCTS FROM BAMBERGER AMCO POLYMERS (the "Distributor") FOR USE IN MEDICAL APPLICATIONS:**

"DISTRIBUTOR PARTIES" shall mean the Distributor and its employees, contractors, customers, or agents.

You agree to inform Distributor if you intend to purchase or obtain a sample of TotalEnergies' resins for any medical application, medical device or medical device component (collectively "Medical Application"). Distributor agrees to inform Seller of such event.

You are to provide written specifications for the resin materials to Distributor and inform Distributor the intended use and application of the Product as well as the type of medical device or medical device component, the U.S. Food and Drug Administration ("FDA") Class, and pertinent information concerning the FDA approval status. Distributor shall provide TotalEnergies such specifications and information provided by you.

You are solely responsible for the performance of biocompatibility testing appropriate to the intended end use of resin materials for medical devices or medical device components or any other medical applications. Biocompatibility evaluations are designed to assess various biological models with the test material or a suitable extract. The specific evaluation program is dependent on the nature, degree, frequency and duration of the resin material's exposure to the body. This evaluation must include, as applicable, testing for suitability as to contact with body tissue and/or storage of solutions/liquids, including but not limited to, medication, blood or other bodily fluids. It is incumbent upon you to perform the appropriate biocompatibility tests to determine safety, efficacy and regulatory compliance. TotalEnergies is not responsible for determining whether its resin materials are biocompatible or suitable for your medical devices, medical device components or medical applications.





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You are fully and solely responsible for the selection and suitability of appropriate resin materials for use in medical applications, and the design, manufacturing and biological evaluation of a finished medical device or medical device component.

You are solely responsible to ensure suitability for use and application of TotalEnergies' resin material following any changes or alterations in the resin material that may occur as a result of handling, processing, application, assembly or integration of TotalEnergies' resin material into a medical application, a medical device or medical device component.

You are solely responsible for appropriate notification to, and approval of use by the FDA of TotalEnergies' resin materials in a medical application, medical device or medical device component. You agree to comply with all FDA and medical device rules and regulations, the Federal Food, Drug and Cosmetics Act, as amended, as well as all other applicable statutes, rules and regulations.

4. **You shall notify Bamberger Amco Polymers and TotalEnergies in writing within five (5) working days or as soon as practicable whenever you learn of or receive: (i) any potential or actual complaint or notice of same; (ii) report(s) pursuant to any Medical Device Reporting regulations; or (iii) any FDA recall relating to your medical application, medical device or medical device component containing TotalEnergies' resin material.**

The suitability of TotalEnergies' resin material in a given end-use environment is dependent upon various conditions including, but not limited to, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is your responsibility as the medical device or medical device component manufacturer to evaluate your final product under actual end-use requirements. You agree to adequately advise and warn your purchasers and end-users of any limitations, risks, hazards, or dangers of your finished product and to disseminate any and all appropriate and required information and data to your purchasers and end-users.

Single use medical devices are not suitable for multiple uses. If the medical device or component is designed for multiple uses, it is your responsibility as the medical device manufacturer to determine the appropriate number of permissible uses by evaluating the medical device or medical device component under actual sterilization and end-use medical conditions and to adequately advise and warn your purchasers and/or end-users of any limitations, risks, hazards or dangers thereof.

**TOTALENERGIES MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, CONCERNING BIOCOMPATIBILITY AND/OR SUITABILITY OF TOTALENERGIES' RESIN MATERIALS FOR MEDICAL APPLICATIONS, MEDICAL DEVICES, OR MEDICAL DEVICE COMPONENTS.**

