

ZYLAR<sup>®</sup> 631 has been tested by an independent laboratory to determine if it meets the requirements of the United States Pharmacopeia (USP) and International Organization for Standardization (ISO) 10993: Biological Evaluation of Medical Devices.

Specific tests include the following:

### **Physico-Chemical Test**

ZYLAR<sup>®</sup> 631 has been tested to determine if it meets the requirements of the United States Pharmacopeia (USP) Physico-Chemical Tests, Plastics. The tests performed were "Non-Volatile Residue", "Residue on Ignition", "Heavy Metals" and "Buffering Capacity". The resin met the USP requirements for all of the above tests.

### **USP Class VI / ISO 10993**

ZYLAR<sup>®</sup> 631 has been tested to determine if it meets the requirements of the United States Pharmacopeia (USP) Biological Reactivity Test, in vivo and was found to meet the requirements of the Class VI Plastic (at 50°C). This test covers the requirements under ISO 10993 of Irritation / Intracutaneous Reactivity, Acute Systemic Toxicity and Short Term Implantation.

### **Cytotoxicity and Hemolysis In Vitro**

An in vitro biocompatibility study, based on the International Organization for Standardization 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: in vitro Methods guidelines, was conducted on ZYLAR<sup>®</sup> 631. The test extract showed no evidence of causing cell lysis or toxicity.

In addition, ZYLAR<sup>®</sup> 631 was also found to be "nonhemolytic" in the in vitro Hemolysis test.

Test reports will be provided upon request.

In its unmodified state, ZYLAR 631 meets the requirements of the above tests and therefore is acceptable for use in medical applications. However, if any alterations in formulation occur from its resin state to future plastic end-product state, these specifications cannot be guaranteed. In addition, although this resin met the requirements, the customer is responsible for obtaining appropriate testing and approvals on the final end-product.