



ZYLAR 530 has been tested by an independent laboratory to determine if it meets the requirements of the International Organization for Standardization (ISO) 10993: Biological Evaluation of Medical Devices. A copy of the test results is available upon request. Details of tests and results are provided in the Appendix.

ZYLAR 530 Clear meets the requirements of all the ISO 10993 tests except the Sensitization and Pyrogenicity tests (not yet tested). However, if ZYLAR 530 is modified in any way, ISO 10993 requirements cannot be guaranteed. In addition, although ZYLAR 530 has passed the ISO 10993 test, the customer is responsible for obtaining ISO 10993 testing on the final end-product state.

Summary of Tests Conducted

The following tests were conducted on ZYLAR 530 unless otherwise noted. This information is intended as a quick reference guide only. Contact Styrolution for specific test results and applicability.

- ✓ USP Physico-Chemical Test
- ✓ Cytotoxicity
- ✓ Hemolysis In Vitro
- ✓ USP Class VI
 - Biological Reactivity Test, in vivo
 - Irritation/Intracutaneous Reactivity
 - Acute Systemic Toxicity
 - Short Term Implantation

Additional Technical Bulletins are available at www.zylar.com or from Customer Service.



APPENDIX

USP Physico-Chemical Test

ZYLAR 530 has been tested to determine if it meets the requirements of the United States Pharmacopeia (USP 23) Physico-Chemical Tests, Plastics. The tests performed were "Non-Volatile Residue", "Residue on Ignition", "Heavy Metals" and "Buffering Capacity". The resins met the USP requirements for all of the above tests.

Cytotoxicity

An in vitro biocompatibility study, based on the International Organization for Standardization (ISO) 10993: Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity: in vitro method guidelines was conducted on ZYLAR 530. In the study, the test extracts showed no evidence of causing cell lysis or toxicity.

Hemolysis In Vitro

Zylar 530 was found to be "non-hemolytic" in the in vitro Hemolysis test.

USP Class VI Status

ZYLAR 530 has been tested to determine if it meets the requirements of the United States Pharmacopeia (USP 23) Biological Reactivity Test, in vivo, and was found to meet the requirements of the Class VI Plastic (at 50 °C). This test covers the ISO 10993 requirements for Irritation/Intracutaneous Reactivity, Acute Systemic Toxicity and Short Term Implantation.