EASTMAN

FDA/ISO 10993 and USP Biological Evaluation Testing for *Eastalloy* DA003-8999K Polymer

	Eastalloy DA003-8999K Polymer
Prior to testing, samples sterilized by:	Gamma
Cytotoxicity	√
Sensitization	√*
Systemic Toxicity (Acute)	√
Hemocompatibility *In vitro* hemocompatibility assay Hemolysis (direct contact)	 √ √
USP Physico-chemical	√
USP Systemic Injection	√
USP Intracutaneous Injection	√
USP Implantation	√

AMES Mutagenicity Study

√ = Meets ISO 10993 and/or USP Class VI biocompatibility requirement

***also tested following eto sterilization**

It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product in order to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized by either the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1 "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices, or (3) as any critical component in any medical device that supports or sustains human life.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1 "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (sub-acute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available upon request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

The suitability of an Eastman product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

For additional information, please contact your Eastman sales representative or the appropriate Eastman marketing subsidiary.