



December 20, 2012

RE: Biocompatibility Status of PEBAX® 5533 SA01 MED

To Whom It May Concern,

This letter provides our assurance that PEBAX® 5533 SA01 MED Product has met the testing requirements for USP Class VI and ISO 10993-5 Cytotoxicity. Unless Arkema otherwise expressly agrees by written contract, the Arkema trademarks and the Arkema name shall not be used in conjunction with customers' medical devices, including without limitation, permanent or temporary implantable devices, and customers shall not represent to anyone else, that Arkema allows, endorses or permits the use of Arkema products in such medical devices. Further, **all implantable medical devices, whether permanent or temporary, carry a risk of adverse consequences.** With regard to implantable medical devices, you should not rely upon the judgment of Arkema. Any decision regarding the appropriateness of a particular medical device in a particular medical application or for a specific clinical use should be based upon the judgment of your physician, medical device supplier and the United States Food & Drug Administration. Unless otherwise specifically stated by Arkema in writing, Arkema does not perform clinical medical studies on implantable medical devices. Arkema cannot weigh the benefits against the risks of a device and does not offer a medical judgment on the safety or efficacy of use of any Arkema product in a medical device.

Further, biocompatibility testing of Arkema products related to USP Class VI and certain requirements of ISO Standard 10993-1 cannot assure the biocompatibility of final or intermediate products made from Arkema products or the suitability of such products for their use in medical applications, i.e., the test data cannot be used to conclude that any medical devices manufactured from Arkema products meet the requirements of USP Class VI and ISO Standard 10993-1. It is the sole responsibility of the manufacturer of final end-use (and finished) products to conduct all necessary tests (including biocompatibility tests) and inspections and to evaluate the final product under actual end-use requirements.

We trust this information is responsive to your request. If you have any questions, please feel free to contact me at 610-205-7045 or [christine.trumpfheller@arkema.com](mailto:christine.trumpfheller@arkema.com).

Sincerely,

Christine M. Trumpfheller  
Product Safety and Regulatory Affairs Manager

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