LANXESS Corporation Guidelines for Medical Application of LANXESS Products

1. All LANXESS resins [hereinafter “Product(s)”] designated as “medical-grade” have met the requirements of the FDA-Modified ISO-10993, Part I “Biological Evaluation of Medical Devices” tests with human tissue contact time of 30 days or less. 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. *ONLY THESE PRODUCTS MAY BE CONSIDERED CANDIDATES FOR APPLICATIONS REQUIRING BIOCOMPATIBILITY.* No “medical-grade” Product will be made available for sale until successful completion of the above testing by LANXESS.

2. Regrind resins must not be used in medical applications requiring biocompatibility.

3. It is the responsibility of the medical device, biological product or pharmaceutical manufacturer (“Manufacturer”) to determine the suitability of all component parts and raw materials, including any LANXESS Product, used in its final product in order to ensure safety and compliance with FDA requirements. This determination must include, as applicable, testing for suitability as an implant device and suitability as to contact with and/or storage of human tissue and liquids including, without limitation, medication, blood or other bodily fluids.

4. Under no circumstances may any LANXESS Product be used in any implant applications (cosmetic, reconstructive or reproductive). Nor may any LANXESS Product be used in any other bodily implant applications or any applications involving contact with or storage of human tissue, blood or other bodily fluids, for greater than 30 days, based on the FDA-Modified ISO 10993 tests.

5. The suitability of a LANXESS Product in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses or 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.

6. Single-use medical devices made from a LANXESS product are not suitable for multiple uses. If the medical device is designed for multiple uses, it is the responsibility of the Manufacturer to determine the appropriate number of permissible uses by evaluating the device under actual sterilization and end-use conditions and to adequately advise and warn purchasers and users thereof.

7. The sterilization method and the number of sterilization cycles a medical device made from a LANXESS product can withstand will vary depending upon type/grade of product, part design, processing parameters, sterilization

temperature and chemical environment. Therefore, the Manufacturer must evaluate each device to determine the sterilization method and the number of permissible sterilization cycles appropriate for actual end-use requirements and must adequately advise and warn purchasers and users thereof.

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