

SciLog D/N: 3148

Revision: A

Title: USP Class VI Material Compliance Statement for SciLog Disposable Sensors

Release Date: 08/06/10

Issued By: AWD

This document applies to the following part numbers: 080-594PSX-5, 080-595PSX-5, 080-596PSX-5, 080-597PSX-5, 080-599PSX-5, 080-694PSX-5, 080-695PSX-5, 080-696PSX-5, 080-697PSX-5, 080-699PSX-5, 080-794PSX-5, 080-795PSX-5, 080-796PSX-5, 080-797PSX-5, 080-799PSX-5

(Lot Specific Documents are available upon request, preferably at time of order.)



August 16, 2007

Re: USP Class VI Testing of Udel® P-1700 NT 11 MG

Thank you for your interest in Solvay Udel® P-1700 polysulfone, manufactured by Solvay Advanced Polymers, L.C.C.

Please be advised that USP Class VI testing has been completed for Udel® P-1700 NT 11 MG. The results indicate that the specific lot tested did not yield extractants which were toxic or irritating upon either acute systemic or acute intracutaneous administration. Similarly, no significant adverse reactions were evident upon intramuscular implantation of this material. In addition, the test material showed no evidence of causing cell lysis or toxicity, and was not considered hemolytic. Therefore, Udel® P-1700 NT 11 MG Lot P070484 is in compliance with *U.S. Pharmacopeia* (USP) criteria for a Class VI plastic.

Enclosed please find the Certificate of Compliance, USP Biological Tests, Class VI, for Udel® P-1700 NT 11, Medical Grade.

I trust this information addresses your concerns. If you have further questions, please feel free to contact me by telephone at 770-772-8552, or by facsimile at 770-772-8726, or by e-mail at carrie.mcmichael@solvay.com

Sincerely,

Carrie McMichael
Product Stewardship Manager

Attachment