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## **SterilMed Achieves Exemplary Results in Routine FDA Audit**

Maple Grove, Minnesota, October 5, 2006 – SterilMed announced that it has successfully concluded their third bi-annual FDA audit after a routine on-site inspection in August. After three days of combing through documentation, the FDA auditor issued no observations, corrective actions or citations.

The comprehensive audits involved all SterilMed systems, including elements of the complaint and CAPA system, design history files, production and process controls, as well as overall company management. FDA inspectors evaluated internal documentation supporting SterilMed quality systems and the way it does business in addition to spending time on the production floor to observe all device reprocessing. As a third-party reprocessor of single-use medical devices, SterilMed complies with the same standards as leading medical device manufacturers.

Brian Sullivan, SterilMed's CEO/President, commented "These exemplary results are quite rare in the medical device industry. Medical device manufacturers, as a heavily regulated industry, are audited by the FDA on no less than a biannual basis. For these types of unannounced audits, FDA auditors often issue formal observations, or even worse, a warning letter requiring the manufacturer to address any deficiencies within a specified time period. These findings support the ethical and quality manner that SterilMed conducts business and its compliance with FDA regulations."

### *About SterilMed*

SterilMed is a leading third-party reprocessor of single-use medical devices, providing the highest quality service to hospitals and other facilities nationwide. State-of-the-art services are designed to provide the highest cost savings, levels of service, greatest clinical staff acceptance, superior support, and the most rigorous science in the industry. SterilMed offers a uniquely integrated approach to medical device reprocessing that ensures the most streamlined logistics and the most rigorous quality approach enabling hospitals and medical facilities to reduce device cost and to decrease medical waste. SterilMed complies with the same standards as leading medical device manufacturers, the FDA Quality System Regulation (QSR) and is ISO 13485 certified.

For further information about SterilMed call 888-541-0078 or connect to [www.sterilmed.com](http://www.sterilmed.com).