

JAN LANG

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Network Contracting Activity 8

Bay Pines VA Healthcare System

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Dear Jan:

Please accept this letter stating that we are competitive and consistent with our pricing for all sites within the VA Healthcare System and notice that Siemens Industry, Inc. is the sole source of Class II Registered Medical Device Deionized Water Tanks in the Florida area.

“Siemens Industry, Inc. Industry, Inc., Type 1, Ultra Mixed Bed DI resin tanks are regenerated at the Siemens Industry, Inc. Industry, Inc. facility located in Jacksonville, Florida which is registered with FDA as a Medical Device Establishment (Registration number 1064564). The Siemens Industry, Inc. Industry, Inc. quality program is compliant with the FDA Quality System Regulations (21 CFR, Part 820).”

Siemens Industry, Inc. is the only authorized contractor with trained service technicians able to complete service with the factory owned vessels. Siemens Industry, Inc. is the only vendor able to regenerate the service deionization vessels. No other contractor is qualified or allowed to service the deionization system. The vessels are leased assets that are owned by Siemens Industry, Inc., these assets must be controlled and the regenerated through our Class II medical facility process.

Siemens Industry, Inc. Reverse Osmosis System is registered under our 510K registration. This registration includes all pre treatment equipment and cartridge filters, as well as the reverse osmosis unit, the distribution system, the storage reservoir, the QSR rated Service Deionization tanks, quality monitoring devices, auto divert devices, Ultraviolet light, and the Final Ultra Filtration component of the system. The system design meets all FDA requirements and AAMI recommendations with regard to Hemodialysis Water Purification System. Other equipment vendors provide a reverse osmosis unit that might be 510K registered; however, all of the other components are not registered. This results in inferior components and materials of construction that are unreliable, manufactured cheaply with performance shortfalls and quality issues with no longevity. The other final result is a non compliant water system in terms of the entire "system design" not meeting 510K registration requirements.

Siemens Industry, Inc. QSR Tanks that are required in the Hemodialysis Water Purification System design are regenerated at Siemens Industry, Inc. FDA Registered facility in Jacksonville, Florida. This FDA approved registration qualification is awarded through a stringent periodic auditing system by the FDA to check for sound regeneration practices. These include adequate segregation practices, the assurance that QSR Protocol requirements are met during regeneration, the presence of sound / documented regeneration practices, the presence of a QSR approved Deionization Tank Flush stand. Siemens Industry, Inc. required FDA certification documentation is included in this offering for your review. No other equipment provider can provide QSR tanks regenerated at an FDA facility as part of their equipment package offering, while also meeting all of the VA requirements.

As always, Siemens Industry, Inc. is pleased to have the opportunity to be of continued service to the Department of Veterans Affairs, Bay Pines VA Medical Center and hopes to continue providing excellent quality and reliable service to your site.

Please call me if you have any questions, or require additional information.

Sincerely,

Larry W. Carder
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FOR SERVICE CALL 1-800-466-7873