

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>\$150K)**

Acquisition Plan Action ID: VA242-18-AP-4871

1. Contracting Activity and Agency:

Department of Veterans Affairs
Network Contracting Office 2
76 Veterans Avenue
Bath, NY 14810

Department of Veterans Affairs
VA Medical Center
400 Fort Hill Avenue
Canandaigua, NY 14424

VISN 2
2237: 528-18-2-5122

2. Nature and/or Description of the Action Being Processed:

The Department of Veterans Affairs, Network Contracting Office 2, and the VA Medical Center in Canandaigua, NY anticipate a new, single manufacturer (brand name only per FAR 6.302-1(c) firm fixed price procurement action for Getinge manufactured sterilizers and associated items. The equipment identified in paragraph 3 below will be purchased and installed in the Sterilization Processing Department (SPD) at the new Rochester (NY) Outpatient Clinic (ROPC) and will be used for the sterilization of reusable medical equipment.

3. Description of Supplies/Services Required to Meet the Agency's Needs:

Estimated Total Cost: TBD

The new Rochester Outpatient Clinic is scheduled to fully open April 2019. The Rochester VA facility has a requirement to procure new equipment for the SPD operation as well as trade in old units where opportunities exist to maximize costs savings. For the purpose of this SOW the new Rochester Outpatient Clinic requires to outfit the Sterile Processing Services Department. Reference the below brand name unit section for complete equipment listing. Cut sheets specific to the brand name make and model were provided to the developer to avoid construction delays. Equipment must be fully compatible with current site utilities and plumbing; no adjustments in construction can be made without extreme impact on operations and finances.

The equipment required for a fully functioning SPD operation at the new outpatient clinic includes the following:

Project Room 1966 Quantity 2 Washer- Disinfector Units

Model Getinge 8668 Washer-Disinfector, part of the new User-Centric design for Getinge products, is intended for the cleaning and thermal disinfection of reusable surgical instruments and utensils. Rotating spray arms between each level of goods, in addition to well-balanced water pressure, help

provide unmatched cleaning without using hold-down covers. Industry leading chamber size, User-Centric controls and ergonomic accessories contribute to the higher throughput and efficiency. Optimized water fill feature and dryer heat exchanger minimize utility consumption. Standard features of this model include: double power glass doors; electric heated sump; intermediate level thermal disinfection; vented drying exhaust; three chemical dosing pumps; and drain discharge cool-down. Wired for 208V connection. Includes STAT Program that allows 30 minute cycle time with optimum utilities for increased throughput and improved utility efficiency. Other Features Include: • Industry leading 12.3 cu-ft chamber volume for processing up to 18 DIN trays or 12 typical US Trays (20.5"L x 10.5"W x 3.5"H) • STAT Program allows instrument cycle times of less than 30 minutes with optimum utilities • Dual power, vertical sliding, full-view glass door for easy visibility of chamber contents • Dual action drying circulates air through both the spray arm and in the chamber for effective, efficient drying • Electric heated sump with Electric heated booster tank. To include Recess Trim for Two Sides of Two 86-Series Washers.

Project Room 1966 Quantity 2 4-Level Wash Cart

Model 503185000 4-Level Wash Cart 8668/88T/CM320, with removable shelves and spray arms, integrated spray arm blocking plates and prepared for up to six connections for cannula instruments

Project Room 1966 Quantity 4 Transport Trolley

Model SMART Transport Trolley for 8666/8668/88T/CM320 Washers

Project Room 1967 Quantity 2 Sterilizer Unit

Model 633HC vacuum/gravity, microcomputer-controlled steam sterilizer with up to twenty-one selectable pre-programmed cycles and vertical sliding door. Cycles include gravity wrapped, vacuum wrapped or unwrapped, flash for porous and nonporous items, liquid cycles and a Vacuum Leak Test cycle. Features enhanced control system with a choice of three operating displays. Program settings are protected with supervisor access control. Includes printer that documents cycle information. VOLTAGE Comparable Ranges include options at 208V, 240V, 480V, 380/415V, 600V • With Tracks for Loading Car • 26.5 x 26.5 x 51" Chamber
• With Auto Blow Down • Single Power Door • For Recessing

Project Room 1966 Quantity 3 Loading Carts

Model SMART Loading Trolley Fixed Height 6613 with 600-Series Prevac/Gravity 51" Load Car - Wire Rack style (complete, with 3 shelf layers), and to include Separator Tank, Auto Blowdown, for ES-18/24/30/36/48

Project Room 1966 Quantity 1 Pass-Through Window

Model D990100 Pass-Through Window Assembly for stud & sheetrock walls measuring 4-1/2 to 6-1/8 inches thick

Project Room 1967A Quantity 1 Reverse Osmosis Water Treatment System

LRG 4800-AB, RO Water Treatment System - MP411, 4800 GPD, 208V, FT, w/ Auto Bypass: Getinge MRG and LRG Reverse Osmosis water treatment systems are designed to provide high-quality water for point-of-use applications such as steam generators; medical washer-disinfectors; cart & utensil washers; lab glassware washers; and cage & rack washers. Use of high-quality water to produce clean steam for medical and research sterilizers will extend the life of equipment and stainless steel instrumentation. Use of RO water is also recommended for reprocessing medical devices during final

rinsing and thermal disinfection to eliminate hard water deposits and enhance drying. When used as instructed, Getinge RO systems will eliminate up to 99% of total dissolved solids, volatile organic compounds, water hardness and chlorine additives from municipal water supply. • 4800 Gallons Output per Day • 208V, 60 Hz, 3-Phase • HW & CW Mixing Valve • Standard Float Tank • General Use with Auto Bypass

Project Room 1303 Quantity 1 Fully Automatic Cart Wash Unit

Model Getinge 9100 Washer-Disinfectors are a series of fully automatic, large capacity, floor loading hydro-spray mechanical washers designed for detergent solution cleaning, rinsing, thermal disinfection and drying of transport carts, containers, tote-bins, bowls, basins and other bulk items reprocessed in Healthcare decontamination departments. The 9100 is standard with full-view, power sliding glass doors for pass-through loading and unloading operations. All models feature a vertically mounted, lateral-sweeping jet spray manifold system with 128 spray nozzles mounted along both walls of the chamber, level-walkable floor, automatic power floor tilt to drain loads and integrated heated air drying. Cabinets can be recessed in a shallow 6-inch (150mm) deep pit for level floor loading or mounted directly on the floor with 6-inch high ramps for loading and unloading. Utilities and service access can be specified on the left or right side of the machine. The circulation and heating system are packaged on one side of the machine and includes two peristaltic chemical dosing pumps, enclosed heat exchanger, main wash pump, drain pump, self-cleaning filter and effluent drain cool-down tank. Seismic design is standard with all models. • Model 9128 w/ 112" Chamber • Pit Mounted • Recessed w/ Barrier Trim Panels • Utility Connection Kit • NetCOM communication solution for exporting data to USB storage drive, T-DOC or Getinge Online. To also include- 1 Universal Container & Utensil Wash Cart w/Lid Rack, 1 Transformer for Electric Heat 9100, 80kVA, 1 9100 Instrument Wash Option; includes trolley manifold docking system in floor, add detergent pumps for enzyme and lube, program and HEPA filter.

Project Room 1303 Quantity 1 Cart Loader Manifold docking wash-cart

Model 9100 Instrument Wash Cart; 2-Level Manifold Docking designed to provide cleaning for more heavily soiled items utilizing the manifold docking system and the integrated spray arms that are mounted under each shelf. Cart is available in various configurations to handle different load types (e.g. Transport bins, containers, instruments, etc.)

Project Room 1966 Quantity 1 Stainless Steel Sink Workstation complete with 3 integral sinks

Model HW673/6 Stainless Steel Sink Workstation complete with 3 integral sinks, externally operated drain valves, 4" High backsplash, and 1/8" drip reducing marine edge. Available as freestanding or with powered height adjustment. Optional side splash(es) and other fixtures are available. Workflow defined sink and fixture locations. • Three 24" Long Sink Bowls • 10 Feet Long • Powered Height Adjustment • Centered Sinks • Right to Left Workflow • Standard Faucet Left/ Overhead Combo Right • Air Gun • Treated Water Faucet • Water Gun

Project Room 1966 Quantity 1 Stainless Steel Sink Workstation complete with 2 integral sinks

Model HW672/4 Stainless Steel Sink Workstation complete with 2 integral sinks, externally operated drain valves, 4" High backsplash, and 1/8" drip reducing marine edge. Available as freestanding or with powered height adjustment. Optional side splash(es) and other fixtures are available. Workflow defined sink and fixture locations. • Two 24" Long Sink Bowls • 8 Feet Long • Powered Height Adjustment • Centered Sinks • Right to Left Workflow • Overhead Pre-Rinse Combination w/ Faucet • Air Gun • Treated Water Faucet • Water Gun

Project Room 2161 Quantity 4 Ergonomic, adjustable height table

Model HATMANS6L Ergonomic, adjustable height table designed to be used as an accumulation, sorting, preparation and packing station. Hand-crank allows precise adjustment of workstation height to the optimum position for the user using a reliable mechanical gear system. Configured with stainless steel work surface for excellent durability and lockable casters for easy mobility. Modular design allows for flexibility in adding and re-positioning of accessories to optimize productivity and improve workflow. • 72" Long x 36" Deep • Controls Mounted on Left. To include Packing Station Accessory Kit for the 72" Height Adjustable Table. Includes: 12" Deep Shelf, Single Drawer, Storage Bin Rail, Quantity of 4 Storage Bins (3"Wx6"Dx3"H), and Quantity of 3 Storage Bins (6"Wx6"Dx3"H) and Workstation Accessory Kit for the 72" Height Adjustable Table. Kit Includes: Rear Support Frame, Overhead Light, and Horizontal Power Strip.

Project Room 1966 Quantity 2 Ultrasonic Cleaner

The Model 2460UC is a single tank, floor mounted product for cleaning instruments using ultrasonic cavitation in a detergent solution. This product features "hands-free" toe switch start, a powered instrument tray elevator and a lid that opens and closes automatically

4. Statutory Authority Permitting Other than Full and Open Competition:

- (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- (2) Unusual and Compelling Urgency per FAR 6.302-2;
- (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- (4) International Agreement per FAR 6.302-4
- (5) Authorized or Required by Statute FAR 6.302-5;
- (6) National Security per FAR 6.302-6;
- (7) Public Interest per FAR 6.302-7;

5. Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

These sterilization components listed in paragraph 3 above will be installed in very specific areas of a brand new building (Rochester Outpatient Clinic). The area of the new building where the Sterilization Processing Section of the building will be located has been predetermined. The size/utility requirements and other pertinent aspects (plumbing, electrical, cabinetry, office space, etc.) have been taken directly into the detailed design considerations of which the construction contract has been awarded. The final plans required specific measurements for required equipment. Any changes in manufacturer will result in major, multiple change orders in terms of utility requirement changes, placement of utilities, wall locations and required washer/disinfectant solutions. The timeline of the construction process is dependent on the delivery of the specific equipment that comprise the SPS operation.

6. Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

Contracting Officer has determined that a brand name requirement is justified given the architecture and engineering design specifications. A Notice of Intent to Sole Source will be posted advising vendors in Classification Code 65 (medical equipment) of the intent to purchase the items on a brand name only basis per FAR 6.302-1(c).

7. Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:

If more than one offer is received, the proposals will be compared against one another as well as the Independent Government Cost Estimate (IGCE) and a fair and reasonable pricing determination will be made. If only one offer is received, the contracting officer will request pricing data from the vendor pertaining to previous awards to VA facilities and a price analysis will be conducted to determine fair and reasonable in accordance with FAR 6.303-2(b)(7).

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

As described in Section 6 above, market research, in accordance with FAR Part 10, will be conducted by synopsis of the proposed acquisition, advising industry of the pending acquisition and soliciting inquiries from interested parties.

A comprehensive search was conducted on the Veterans Information Pages (VIP) resulted in three (3) findings for the key word "Getinge"

Additionally, a search on FPDS-NG for "Getinge" and "sterilizer" resulted in many "hits", including one for a Service Disabled Veteran Owned Small Business (SDVOSB).

9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

Statement of Work Attached

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

Getinge USA, LLC	Large Business
Trillamed, LLC	SDVOSB

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

In this instance, CO determines that a brand name requirement is valid and appropriately justified. Small business authorized distributors have been requested as required.