

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval

For

Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VISN 23, St. Cloud VA Health Care System, 4801 Veterans Drive St. Cloud, MN 56303, 618-13-1-040-0001

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

A new firm fixed price contract for a Ventricular Assist Device System that is capable of minimal priming volume, surface area, haemolytic index and mean transit time, no stagnant blood zones and less hot spots, hydraulic optimized flow channels, spiral housing for best flow ratio and low-friction one-point bearing.

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

Two ROTAFLOW Ventricular Assist Device Systems part #70105.1712 plus components from Maquet Medical Systems USA [REDACTED] Anticipated delivery is within 60 days ARO.

**Estimated Dollar Value:** [REDACTED]

**Required Delivery Date:** ASAP

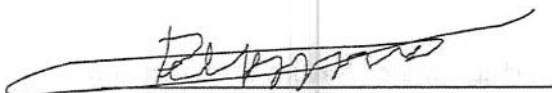
4. **Statutory Authority Permitting Other than Full and Open Competition:**

- ☒ (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):** This is a

proprietary and to our knowledge the MAQUET MEDICAL SYSTEMS USA ROTAFLOW Ventricular Assist Device System products are not compatible with other existing MVAHCS brands or products. The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. The MVAHCS requests sole source to use MAQUET MEDICAL SYSTEMS USA because they are the parent company, original manufacturer and sole distributor of ROTAFLOW Ventricular Assist Device System products and services.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** The ROTAFLOW Ventricular Assist Device System is not available on GSA or any other sources based on internet search. MAQUET MEDICAL SYSTEMS USA is the parent company, original manufacturer and sole distributor of ROTAFLOW Ventricular Assist Device System products and services.
7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** Price is fair and reasonable based on recent purchases of other Ventricular Assist Device System products and services.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** The ROTAFLOW Ventricular Assist Device System is not available on GSA or any other sources based on internet search. MAQUET MEDICAL SYSTEMS USA is the parent company, original manufacturer and sole distributor of ROTAFLOW Ventricular Assist Device System products and services.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Model ROTAFLOW has the following needed unique features:
- Spinning rotor with flow channels which impacts rotary motion to the incoming blood, directing it through a spiral housing to the outflow port.
  - The rotor is suspended by a permanent magnetic field.
  - The one-point sapphire bearing and the low priming volume combined with the spiral volute chamber assure a smooth blood handling and hydraulic optimized blood flow.
  - The renunciation of a shaft and seals make the ROTAFLOW an ideal centrifugal pump.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** MAQUET MEDICAL SYSTEMS USA, Chris Byrne, 800-777-4222, [info@maquet.com](mailto:info@maquet.com)
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:** The MVAHCS continues to actively seek qualified contractors to provide required supplies and services.
12. **Requirements Certification:** I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.




**Name:** Petroula Hansen  
**Title:** Biomedical Engineer  
**Facility:** Biomedical Instrumentation Service

6/11/2013  
Date

13. **Approvals in accordance with FAR 6.304**

- a. **Contracting Officer's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

  
Wendy Hoeschen  
Contracting Officer

7/3/13  
Date

- b. **NCM/PCM (Required \$3K and above):** I certify the justification meets requirements for other than full and open competition.

  
Jeri Jenkins  
Facility Contract Manager, NCO 23

14 JUN 13  
Date