

**JUSTIFICATION FOR SINGLE SOURCE AWARDS IAW FAR 13.106-1**  
(OVER MICRO-PURCHASE THRESHOLD(\$3K) BUT NOT EXCEEDING THE SAT (\$150K))

IAW [FAR13.104](#), COs must promote competition to the maximum extent practicable to obtain supplies and services from the source whose offer is the most advantageous to the Government, considering the administrative cost of the purchase. When competition is not practicable, IAW [FAR13.106-1\(b\)](#), COs solicit from a single source for purchases not exceeding the simplified acquisition threshold. COs may solicit from one source if the CO determines that the circumstances of the contract action deem only one source reasonably available (e.g., urgency, exclusive licensing agreements, brand-name or industrial mobilization). IAW [FAR13.106-3\(b\)\(3\)](#), COs are required to include additional statements **explaining the absence of competition** (see [13.106-1](#) for brand name purchases) if only one source is solicited and the acquisition does not exceed the simplified acquisition threshold (does not apply to an acquisition of utility services available from only one source) or supporting the award decision if other than price-related factors were considered in selecting the supplier. This template when completed can be used to document single source awards IAW [FAR13.106-3\(b\)\(3\)](#). Note: Statements such as "only known source" or "only source which can meet the required delivery date" are inadequate to support a sole source purchase.

<b>1. PURCHASE REQUEST OR REQUISITION NUMBER:</b> 766-16-3-400-0877	<b>1A. PROJECT/TASK NUMBER</b>	<b>1B. ESTIMATED AMOUNT:</b> 
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**2. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES REQUIRED AND THE INTENDED USE:**

1. DESCRIPTION: MINIMED PARADIGM INFUSION PUMP, 3 ML RESERVOIRS **#MMT-332A**  
NDC/Stock#: 76300-0332-10  
UNIT: 10 per box  
QTY: 800 BOXES

2. DESCRIPTION: Set, Infusion Minimed **#MMT-378**  
NDC/Stock#: 76300-0378-10  
UNIT: 10 per box  
QTY: 50 BOXES

3. DESCRIPTION: Reservoir, Minimed **#MMT-326A**  
NDC/Stock #: 07630-0326-10  
UNIT: 10 per box  
QTY: 300 BOXES

**3. UNIQUE CHARACTERISTICS THAT LIMIT AVAILABILITY TO ONLY ONE SOURCE, WITH THE REASON NO OTHER SUPPLIES OR SERVICES CAN BE USED:**

Once a physician determines that their treatment plan for a patient includes an insulin pump, the Prosthetic Department of the VA Medical Center issues a Medtronic Minimed wearable constant insulin delivery system to the patient. These devices were researched, tested, and approved by the VA as the preferred item for this treatment. Neither Medtronic nor a physician will validate or waive liability of using other than Minimed products in conjunction with the issued pump. Although there are many infusion items designed to be interoperable with all pumps, Medtronic contends that they cannot ensure that the prescribed medicine is delivered when third party parts are used with their pump. According to Medtronic, manufacturer specific, non-interchangeable, parts for administering the insulin are required to ensure proper dosage.

If the CMOP National File entry has a specific brand or item number in the prescription description, the CMOP is

ONLY allowed to dispense that exact item match. The VA Doctors writing prescriptions do so based on clinical need and write the prescription accordingly to provide critical patient care. The pump works in conjunction with the associated tubes to deliver the insulin as prescribed by a physician. The manufacturer cannot guarantee that the prescribed medical dose can or will be delivered as prescribed if any part of the Minimed device is NOT manufacturer approved. Not using the entire Minimed package (tubes, pump, and injection ports) could pose a threat to the patient as the prescribed amount cannot be guaranteed. The accessories are a part of a highly specialized insulin delivery system that can use other than manufacturer accessories but it is not recommended. If third party accessories are used, Medtronic cannot ensure the insulin delivery device is delivering insulin as prescribed by a physician. Based on this inability to ensure the prescribed dose is being delivered accurately, using third party accessories can put patient care in jeopardy. Mildly low blood sugar levels are somewhat common for people with diabetes; however, severely low blood sugar levels can be life-threatening. They may lead to seizures and nervous system damage. Immediate treatment is critical. It is imperative that the pump functions correctly.

**4. REASON THAT SUGGESTED SOURCE IS THE ONLY SOURCE, WHICH CAN PROVIDE THE SUPPLIES OR SERVICES:**

Thorough market research has been conducted and it has been found that these specific Medtronic Minimed Reservoir pumps, inserts, and infusion sets found on this purchase request are not found to be on VA NAC or GSA contract.

There are several small business and SDVOSB wholesaler/distributors that can provide these Medtronic items on the open market.

**5. DESCRIPTION OF MARKET RESEARCH CONDUCTED AND RESULTS OR STATEMENT WHY IT WAS NOT CONDUCTED:**

After searching NAC & GSA, there are no available contracts for any of the items requested. A search of the Center for Veteran Enterprise Vendor Information Pages indicates there are 77 SDVOSB or VOSB vendors which are engaged in the manufacture of pharmaceuticals. A query at the SBA Dynamic Search portal returned 949 possible small business vendors. However, these vendors are not engaged in manufacture, but are distributors for large business wholesalers. Because the Government is not allowed to do business using Wholesale Trade or Retail Trade NAICS codes, searches must be conducted using the manufacture NAICS code of 325413 In Vitro Diagnostic Substance Manufacturing.

**6. Contracting Officer's Certification:** *Purchase is approved in accordance with FAR13.106-1(b). I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.*

Signature: Melissa K  
Name: \_\_\_\_\_  
Title: Brau 440013  
Facility: \_\_\_\_\_

Digitally signed by Melissa K Brau 440013  
DN: dc=gov, dc=va, o=internal,  
ou=people,  
0.9.2342.19200300.100.1.1=melissa.brau@  
va.gov, cn=Melissa K Brau 440013  
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Date: \_\_\_\_\_