

ITEM OPPORTUNITY SYNOPSIS

Name of the item to be scouted: Silicone Injected Molded Gasket

State item to be used in: Georgia

Describe the Item:

Please describe the item application/the end use of item. The item is a gasket for a Class 3 medical device. The client is seeking a domestic manufacturing partner who can injection mold silicone for medical devices.

Supplier Information:

Type of Supplier being sought (select from list below)

Manufacturer

Contract Manufacturer

Distributor

Other (please specify)

Reason for scouting submission (select from list below)

2nd Supplier

Price

Re-Shore

Past supplier no longer available

New Product Startup

Other (please specify)

Summary of Technical Specifications and Performance Requirements:

Describe the manufacturing processes (elaborate to provide as much detail as possible). The client currently has a European-based supplier who will vacuum cast the required gasket with RPU11 material in a silicone mold; the resulting gasket does not have the durability required and thus the client is seeking to produce the part from silicone, as an injected molded component, instead. This client is seeking a supplier to partner with on prototypes, design and material specifications, and ultimately production of the part domestically. The gasket shown in the attached photo has an OD of 64mm.

Provide dimensions / size / tolerances / performance specifications of the item. Gasket shown is 64 mm OD

List required materials needed to make the product, including materials of product components, if applicable. Silicone, injection molding proces

Are there applicable certification requirements?

Yes

No

Please Explain:

Are there any applicable regulations that apply to the production of this item?

Yes

No

Please Explain: This is a medical device; applicable FDA regulations.

Are there any other standards, requirements?

Yes

No

Please Explain:

Additional Comments:

Additional technical comments:

Volume and Pricing:

Estimated Potential Business Volume (i.e. #Units per day, month, year): New product, new medical device; indeterminant at this time.

Estimated Target Price / Unit Cost Information: New product, new medical device; client wants to work with a manufacturer on options of material, process and cost.

Delivery Requirements:

When is it needed by? (Immediate, 30 days, 6 months, etc) Product development is on-going; as soon as possible after the 30 day scouting period expires.

Describe packaging requirements (i.e., individually/ group packaging). TBD

Where will this item be shipped? Atlanta, GA

