From: Jennifer.Wu@medtechsolutions.com

To: sales@aeromfg.com

Subject: Custom Titanium Components - Cardiac Device Project MTS-2025-CD47

Date: January 22, 2025, 10:30 AM EST

Hi Team,

We need a quote for custom machined titanium components for our next-generation cardiac monitoring device. Here are the requirements:

COMPONENT DETAILS

• Part Name: Sensor Housing Assembly

• Material: Titanium Grade 2 (commercially pure)

• Quantity: 5,000 units initial order, 20K annually

• Due date for samples: March 15, 2025

SPECIFICATIONS

Parameter	Value
Outer diameter	12.7mm ±0.025mm
Wall thickness	0.8mm ±0.05mm
Internal surface finish	Ra 0.4 μm maximum
External surface	Electropolished per ASTM F86
Thread	M10 x 0.75 internal, Class 6H

CRITICAL REQUIREMENTS

▼ FDA 510(k) manufacturing facility required

☑ ISO 13485 certification mandatory

☑ Biocompatibility testing per ISO 10993

✓ Certificate of Compliance with each lot

Raw material must be certified for medical use

PACKAGING

Individual sterile packaging required. We can provide specific packaging specifications once you confirm capability.

ADDITIONAL NOTES

⚠ Important: This is for an implantable device, so quality is absolutely critical. We've had issues with our current supplier meeting surface finish requirements. Also need full traceability back to raw material certifications.

Please confirm:

- 1. Capability to machine titanium to these tolerances
- 2. Current FDA registration status
- 3. Lead time for initial samples
- 4. Pricing for initial 5K and annual 20K volumes

Thanks,

Jennifer Wu

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