

MEPNN Supplier Scouting Opportunity Synopsis

Section 1: General Information

Scouting Number	2024-402
Item to be Scouted	Medical Device
Days to be scouted	60
Response Due By	02/16/2025
Description	The device is a head-mounted & forehead stabilized ocular & peri-ocular treatment platform for treatment of evaporative dry eye disease in both the doctor office and patient home.
Notify Requester Immediately	No
State item to be used in	Arizona

Section 2: Technical Information

Type of supplier being sought	Contract manufacturer
Reason	New product startup
Describe the manufacturing processes (elaborate to provide as much detail as possible)	Assembly, but components that need to be manufactured or sourced included: Injection molding plastic parts, printed circuit board assembly (PCBA) boards, soft plastics Polyurethane (PU)
Provide dimensions / size / tolerances / performance specifications for the item	Designed to fit adult human heads. Drawings and details can be shared after initial discussion and with a signed NDA. You can see an example here: https://www.eyedetec.com/the-tech/
List required materials needed to make the product, including materials of product components	Plastics, PU, PCBA, head straps
Are there applicable certification requirements?	Yes
Certification(s) required	ISO 13485
Are there applicable regulations?	Yes
Details	US FDA class I and class II
Are there any other standards, requirements, etc.?	Yes
Details	Maintain Design History File
NAICS 1	
NAICS 2	
Additional Technical Comments	Drawings and details can be shared after initial discussion and with a signed NDA.

Section 4: Business Information

Estimated potential business volume	Initially 2,000 - 3,000/ year, growing to ~50,000 units/year in 4 years
Estimated target price / unit cost information (if unavailable explain)	\$100/unit at volume production
When is it needed by?	TBD
Describe packaging requirements	Best available. Delivered undamaged. Specifics discussed in negotiation.
Where will this item be shipped?	Multiple destinations outside US and a warehouse in US

Additional Comments

Is there other information you would like to include?