Zutron Medical
9816 Pflumm Rd
Lenexa, KS 66210

Date

Vendor Evaluation Form

Date:_____

Please complete all applicable sections/information on this survey and return to sender.
Consultants shall complete Sections 1 and 2. All other suppliers shall complete Sections 2 to 15.

SECTION 1: CONSULTANTS ONLY ☐ N/A (Check if not applicable)

Please check the boxes for all applicable documents and attach to the survey:
If not applicable or not available, check the N/A box.

☐ CV (Curriculum Vitae)	☐ N/A
☐ Consulting Agreement	☐ N/A
☐ Separate Quality Agreement	☐ N/A
☐ Non-Disclosure Agreement	☐ N/A

SECTION 2: SUPPLIER PROFILE

Supplier Name: _____
Subsidiary of (if applicable): _____
Address: _____
_____
_____

Phone: _____
Fax: _____
Web Address: _____

Product/Service Provided: _____
_____

Management

Title	Name	Years in Position
Executive (CEO):	_____	_____
Financial (CFO):	_____	_____
Operations (COO):	_____	_____

Please provide your organizations Quality and Regulatory contacts below. FMSU-ESD may need to contact them for further clarification of Quality System, ISO or FDA related issues:

	Name	Number
Quality:	_____	
Regulatory:	_____	

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SECTION 3: GENERAL INFORMATION ☐ N/A (Check if not applicable)

Number Buildings/Locations: _____ Total Plant Square Feet: _____
Number of Employees: _____ Number of Shifts: _____
Number of Years in Business: _____ Hours of Operation: _____
Union: ☐Yes ☐No (check one) If yes, date of contract expiration: _____
D & B #: _____
Business Certifications: (i.e. Small Disadvantaged Business) _____

SECTION 4: CERTIFICATIONS AND REGISTRATIONS ☐ N/A (Check if not applicable)

1. Is the organization registered to ISO 9000 standards? ☐Yes ☐No
   If yes, which standard? _____
   i. Name of registering body: _____
   ii. Registration number: _____
   iii. Scope and locations covered: _____
   iv. Effective date: _____
   v. Expiration date: _____
   vi. Date and Type of last audit: _____
   a. Was there "Non-Conformance Observation(s)" issued against your company? ☐Yes ☐No _____
   If yes, please list Non-Conformance(s) _____
   _____
   b. Date of next audit _____
2. Is the organization registered with the U.S. FDA? ☐Yes ☐No
   If yes, what is the Establishment registration number? _____
3. Has the organization ever been inspected by the U.S. FDA? ☐Yes ☐No
   If yes, when_____
4. Has the organization ever received a 483 or warning letter from the U.S. FDA? ☐Yes ☐No
   If yes, provide a copy of the 483, warning letter and response explaining how the deficiencies were corrected/ addressed.
   _____
   _____
5. Has the organization ever had a Medical Device Reports filed with the FDA against any of your Medical products? ☐Yes ☐No
   If yes, please explain
   _____
   _____

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SECTION 5: QUALITY SYSTEM ☐ N/A (Check if not applicable)

1. Does the organization have a documented quality system? ☐Yes ☐No
   If yes, provide copy of quality manual
2. Does the organization have an organizational chart indicating the lines of authority and responsibility for quality personnel and functional areas? ☐Yes ☐No
3. Does the organization have a Quality Training program? ☐Yes ☐No
   If yes, are the training records maintained? ☐Yes ☐No
4. Does Executive Management take an active role in quality planning, quality assurance and process improvement? ☐Yes ☐No
5. Does management regularly review the status and adequacy of the quality program? ☐Yes ☐No
6. Are quality metrics such as graphs or charts used to track quality improvements? ☐Yes ☐No
7. Are the Training and Educational requirements identified for all applicable positions? ☐Yes ☐No

SECTION 6: DOCUMENT CONTROL ☐ N/A (Check if not applicable)

1. Are there written procedures for quality control activities? ☐Yes ☐No
2. Are all quality system document releases and changes controlled? ☐Yes ☐No
3. Are there written procedures for the control of customer contract requirements? If yes, provide a copy. ☐Yes ☐No
4. Are relevant documents available at all locations where the related operations are performed? ☐Yes ☐No

SECTION 7: DESIGN CONTROL ☐ N/A (Check if not applicable)

1. Are there written procedures for the control of design activities? ☐Yes ☐No
   If yes, provide a copy.
2. Are design reviews performed, documented and approved by qualified personnel? ☐Yes ☐No
3. Do your procedures ensure that the latest specifications and/or drawings are used? ☐Yes ☐No

SECTION 8: INTERNAL AUDITS ☐ N/A (Check if not applicable)

1. Are there independent internal audits performed on your products, processes, and quality systems? ☐Yes ☐No
   If yes, how often? _____ _____
2. Are Internal Audits performed by Trained Personnel? ☐Yes ☐No

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SECTION 9: MATERIAL CONTROLS ☐ N/A (Check if not applicable)

1. Is stored or shipped material, properly identified and labeled? ☐Yes ☐No
2. Do packaging requirements include provisions for identification of special materials (i.e. limited life, hazardous, etc.) ☐Yes ☐No
3. Is there a system in place to ensure that products are protected from damage and/ or deterioration during storage, handling, and shipment? ☐Yes ☐No

SECTION 10: NON-CONFORMING MATERIAL & CAPA ☐ N/A (Check if not applicable)

1. Are there procedures in place for controlling Non-Conforming material? ☐Yes ☐No
2. Is there a system that exists for material disposition, which includes the re-inspection of repair or reworked product? ☐Yes ☐No
3. Is there a segregated area for Non-Conforming material? ☐Yes ☐No
4. Is there a corrective action procedure in place requiring root cause analysis? ☐Yes ☐No

   If so, is this procedure used for the following:(a-d)

   a. Non-Conforming supplier material? ☐Yes ☐No
   b. Out-of-control processes? ☐Yes ☐No
   c. Failed internal audits? ☐Yes ☐No
   d. Customer complaints / returns? ☐Yes ☐No

SECTION 11: PURCHASING CONTROLS ☐ N/A (Check if not applicable)

1. Are there written procedures for the control of purchasing activities? ☐Yes ☐No
2. Do your purchasing documents include a clear description of the products or services required including references to applicable standards and codes? ☐Yes ☐No
3. Are your purchasing documents reviewed and approved for adequacy and accuracy of specified requirements by appropriate personnel prior to release? ☐Yes ☐No
4. Is there a supplier assessment/certification program? ☐Yes ☐No
5. Are supplier quality records maintained? ☐Yes ☐No

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SECTION 12: INSPECTION AND TESTING ☐ N/A (Check if not applicable)

1. Are your Receiving, In-Process and Final Inspection Records maintained and available for review? ☐Yes ☐No
2. Are your Testing Records documented and are the records maintained and available for review? ☐Yes ☐No
   a. Do the records have actual Test Data (not pass/ fail) ☐Yes ☐No
3. Do records of all Inspections and Tests reflect:
   a. The number of items that pass or fail? ☐Yes ☐No
   b. The types of deficiencies found? ☐Yes ☐No
   c. The corrective action documentation, as applicable? ☐Yes ☐No
   d. Are these records signed by applicable individuals? ☐Yes ☐No

SECTION 13: PROCESS CONTROL ☐ N/A (Check if not applicable)

1. Are there written procedures describing each step of your controlled process activities (i.e. configuration, production, calibration, etc.)? ☐Yes ☐No
2. Are product deviations submitted to the customer for approval prior to shipment? ☐Yes ☐No
3. Is there a documented traceability system that identifies the status of material from inspection to shipment? ☐Yes ☐No
4. Is inspection data used as a basis for investigation, root cause analysis and corrective action, (i.e. scrap, rejects, etc.)? ☐Yes ☐No
5. Do you have a documented calibration system? ☐Yes ☐No
6. Are calibration standards traceable to a Certified or National Standard? ☐Yes ☐No
7. Are the processes validated for that process and are the validation records available for review? ☐Yes ☐No

SECTION 14: SERVICING: ☐ N/A (Check if not applicable)`

1. Does your company have a U.S. Service presence? ☐Yes ☐No

   If Yes, is this group part of your company or a third party service provider

   (if a third party, who are they?): _____
2. Is there a procedure with defined responsibilities for processing customer complaints and ensuring corrective action is taken? ☐Yes ☐No
3. Are there processes in place for ensuring product issues are periodically reviewed and analyzed? ☐Yes ☐No
4. Is product serviced, repaired and tested per written instructions? ☐Yes ☐No
5. Are service records maintained and easily retrievable? ☐Yes ☐No
6. Is there a procedure with defined responsibilities for recalling Non-Conforming products from the field? ☐Yes ☐No

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SECTION 15: AGREEMENTS ☐ N/A (Check if not applicable)

Please check the boxes for all applicable documents and attach to the survey:
If not applicable or not available, check the N/A box.

- ☐ Supplier Agreement ☐ N/A
- ☐ Quality Agreement applicable ☐ N/A
  (May be combined with the Supplier Agreement)
- ☐ Non-Disclosure Agreement ☐ N/A

Completed by:	Name: _____
	Title: _____
	Date: _____

/s/ Jordan Hartong