TITLE: Supplier Survey Checklist

BVI uses the following Supplier Evaluation Survey Checklist to assess potential and existing suppliers' organizational and quality system structure. We ask the supplier to respond to each item appropriately. Additionally, each section includes a "Comments" section to be used for any additional information the supplier feels may be necessary to describe its processes / procedures. Please liaise with your sourcing team or quality contact member if you have any questions.

****ALL FIELDS ARE TO BE FILLED OUT. SECTIONS NOT REQUIRED ARE TO BE MARKED AS N/A. ALL REQUESTED CERTIFICATION IS TO BE SUPPLIED ****

1. General Supplier Information.			
Company Name			
Postal Address			
Telephone		Website	
Fax		Contact e-mail(s)	
Scope of Supply to BVI (Product / Service)			
Are any products being supplied likely to have sourcing issues? Please detail.			
Ownership: ☐ Partnership ☐ Private ☐ Public ☐ Other			
Number of years in business			
Industries Served			
What percentage of your business is focused on products or services for the medical industry?			……. %

2. Third Party Certification Information. Please indicate current certification held.				
Certification	**Yes**	**No**	**N/A**	**Comments – i.e. Indicate timeline to certification if applicable / explain rationale for N/A.**
EC 93 / 42 / EEC (MDD)				
EU 2017 / 745 (MDR)				
EU 2017 / 745 (MDR) transition under way?				
MDSAP				
Competent Authority Registerd?				
ISO 13485				
ISO 9001				
ISO 14001				
ISO 26000				
Labour Standards Assessment System (LSAS)				
Modern Slavery Assessment Tool (MSAT)				
Certificates Attached				
Comments				

****Please provide electronic copies of certification detailed above via return e-mail.****

ISO Registrar Name (Component Manufacturer):	Date of last audit:
Notified Body Name (Device Manufacturer):	Date of last audit:
Competent Authority Name (Device Manufacturer):	Date of last audit:

If you are a contract manufacturer and manufacture of finished medical devices as defined by 21 CFR 820.3 (l), are you registered with the FDA? ☐ Yes ☐ No (if No, describe why)

FDA Establishment Number.	

****Only complete sections 3 to 14 if not ISO 13485 certified.****

Instructions for completing Sections 3 to 14:
Using the following rating system, answer each question by writing or typing in the number that best describes your response in the column "Score." complete all questions as applicable.

Rating:

3 = Procedure or system is thoroughly documented and consistently adhered to.
2 = Procedure or system exists though it may not be fully deployed/ followed.
1 = Procedure or system exists but is rarely followed or in the initial stage of deployment.
0 = No procedure or system exists at this time.
N/A = Not applicable.

- Space is provided after each section for any comments. Please provide any details not described by documents. Additional example documentation may be attached.

3. Contract Review & Document Control	Rating System	Score
3.1. Is there a Quality Manual available that describes quality-related procedures?	0 1 2 3 N/A	
3.2. Is there a procedure to ensure that revision levels are verified for each manufacturing order against the customer purchase order?	0 1 2 3 N/A	
3.3. Is there a procedure requiring customer notification and approval of material, process, or manufacturing site location changes?	0 1 2 3 N/A	
3.4. Is there a master listing identifying current procedures or work instructions and their latest revisions?	0 1 2 3 N/A	
3.5. Is there a procedure for the removal of obsolete documents?	0 1 2 3 N/A	
3.6. Is there a documentation retention procedure?	0 1 2 3 N/A	
Comments:	Max Points: 18	Total:

4. Control of Inspection, Measuring & Test Equipment	Rating System	Score
4.1. Is there a procedure that describes calibration intervals and maintenance requirements for all measurement equipment used to measure part or product conformance?	0 1 2 3 N/A	
4.2. Are all measurement equipment items clearly labeled with the last date of calibration and when due for recalibration?	0 1 2 3 N/A	
4.3. Is all measurement equipment that is not used to measure part or product conformance identified with a "NO CALIBRATION REQUIRED" label or wording to that effect?	0 1 2 3 N/A	
4.4. Are calibration records performed using equipment and gages traceable to the National Institute of Standards and Technology or other suitable standards?	0 1 2 3 N/A	
4.5. Are calibration records maintained for all measurement equipment?	0 1 2 3 N/A	
4.6. If the equipment is found to be out of tolerance during calibration, are there procedures or policies to evaluate the impact it may have had on manufacturing material?	0 1 2 3 N/A	
Comments:	Max Points: 18	Total:

5. Income Inspection	Rating System	Score
5.1. Are incoming materials inspected to all requirements of a purchase order, general specifications, and/or applicable drawings?	0 1 2 3 N/A	
5.2. Are there inspection procedures for incoming materials?	0 1 2 3 N/A	
5.3. Are statistically valid sampling plans with AQL's based upon customer requirements utilized?	0 1 2 3 N/A	
5.4. Is there a procedure for the disposition of discrepant incoming materials?	0 1 2 3 N/A	
5.5. Are there procedures and practices to ensure that incoming materials and rejected materials are kept segregated and secured from accepted material?	0 1 2 3 N/A	
5.6. Is there a procedure that describes how long inspection records are retained?	0 1 2 3 N/A	
Comments:	Max Points: 18	Total:

6. In-Process & Final Inspection	Rating System	Score
6.1. Is in-process and/or final inspection performed on each lot to ensure compliance with all requirements of the customer purchase order, general specifications, and/or applicable drawings?	0 1 2 3 N/A	

6.2. Where inspection and testing are being performed, are there written procedures with statistically valid AQL based sampling plans being utilized?	0 1 2 3 N/A	
6.3. Is there a procedure and policy to ensure that a first article inspection is performed for all applicable dimensions when a part revision, material, or manufacturing process has changed?	0 1 2 3 N/A	
6.4. Is inspection and test data maintained on file and traceable to each lot?	0 1 2 3 N/A	
6.5. Can inspection and test data collected for key specified parameters be summarized to indicate statistical control/consistency for each lot shipped to the customer?	0 1 2 3 N/A	
6.6. Is there a procedure for the identification, segregation, and disposition of discrepant parts and assemblies?	0 1 2 3 N/A	
Comments:	Max Points: 18	Total:

Section 7 is not applicable for distributors

7. Manufacturing & Process Control	Rating System	Score
7.1. Are there written procedures for all manufacturing processes, and do the procedures indicate workmanship criteria, special handling or process conditions, and the specific equipment used?	0 1 2 3 N/A	
7.2. Is a lot traveler (or router) utilized, and does it clearly define all processing and inspection steps for each product lot as it progresses through manufacturing and test? Do the records indicate the completed manufacturing processes with the quantities, names, and dates of those who performed each identified step?	0 1 2 3 N/A	
7.3. Are all software changes validated before approval and issuance, and are there effective controls to ensure that only the most current version can be used?	0 1 2 3 N/A	
7.4. Are all processes validated when the process results cannot be fully verified by subsequent inspection or testing?	0 1 2 3 N/A	
7.5. Is there a preventive maintenance schedule established for all production equipment and tooling, and is it suitable to ensure continuing process capability? Does it include a system for monitoring tool life and the number of parts produced from a tool before maintenance and/or replacement?	0 1 2 3 N/A	
7.6. Are there procedures and practices to prevent contamination or degradation of parts from dust, oil, hazardous substances, or other environmental contaminants?	0 1 2 3 N/A	

Comments:	Max Points: 18	Total:

8. Packaging, Storage & Shipping	Rating System	Score
8.1. Is there a procedure that describes proper handling, packaging, storage, preservation and shipping methods?	0 1 2 3 N/A	
8.2. Are raw materials/parts stored and used on a first-in, first-out (FIFO) basis?	0 1 2 3 N/A	
8.3. Is there a formal procedure or process for material identification, labeling, and segregation?	0 1 2 3 N/A	
8.4. Is there a procedure that describes the handling and expiration date coding of limited life materials?	0 1 2 3 N/A	
8.5. Are finished goods effectively segregated with a manufacturing lot number or a date coding system that includes the part number and revision level?	0 1 2 3 N/A	
8.6. Are labeling, certifications and packaged finished product inspected and verified to ensure compliance with customer requirements before shipment?	0 1 2 3 N/A	
Comments:	Max Points: 18	Total:

9. Corrective & Preventive Action	Rating System	Score
9.1. Is there a procedure for implementing corrective and preventive actions?	0 1 2 3 N/A	
9.2. Is there a follow-up system to identify, evaluate effectiveness and close corrective actions?	0 1 2 3 N/A	
9.3. Is there a log, database, or other system used for trending and/or history of corrective actions?	0 1 2 3 N/A	
9.4. Is there a procedure for the receipt and evaluation of customer complaints?	0 1 2 3 N/A	
9.5. Does the above Procedure include the issuance of return material authorizations (RMA's) and supplier corrective action requests (SCAR's) to the customer?	0 1 2 3 N/A	
9.6. Is quality cost data (scrap, rework, customer returns, etc.) collected, analyzed and shared throughout the organization to drive process improvement and part variability reduction activities?	0 1 2 3 N/A	
Comments:	Max Points: 18	Total:

10. Training	Rating System	Score

10.1. Is there a procedure that defines the responsibilities and training requirements for each position?	0 1 2 3 N/A	
10.2. Have training and development plans been implemented for all employees who have an impact on quality?	0 1 2 3 N/A	
10.3. Are processes operated/performed by qualified employees?	0 1 2 3 N/A	
10.4. Are training records maintained on each employee, including the training course/subject, completion date and trainer name?	0 1 2 3 N/A	
10.5. Are individual training records easily accessible to each employee?	0 1 2 3 N/A	
10.6. Is training being provided to changes that would affect the form, fit, or function within the area?	0 1 2 3 N/A	
Comments:	Max Points: 18	Total:

11. Quality Compliance	Rating System	Score
11.1. Has your company's management established a formal, ongoing continuous quality improvement program?	0 1 2 3 N/A	
11.2. Do you perform internal system audits?	0 1 2 3 N/A	
11.3. Have you established procedures / process to receive, review and evaluate complaints from internal/external customers	0 1 2 3 N/A	
11.4. Have you established procedures defining requirements for top management's review of the quality management system to ensure its continuing suitability, adequacy and effectiveness periodically?	0 1 2 3 N/A	
11.5. Are statistically valid sampling plans with AQL's based upon customer requirements utilized?	0 1 2 3 N/A	
11.6. Do you conduct a process risk assessment (e.g., FMEA, risk analysis)?	0 1 2 3 N/A	
11.7. Do you have a procedure that defines the process for handling Recalls / Field Actions / HHE?	0 1 2 3 N/A	
Comments:	Max Points: 21	Total:

12. Labor & Environmental Standards	Rating System	Score
12.1. Is there a workplace for your employees free from discrimination, harassment, or other forms of abuse?	0 1 2 3 N/A	
12.2. Are there policies to ensure all forms of child, forced, or compulsory labor is prohibited?	0 1 2 3 N/A	

12.3. Are there policies to ensure employees' right to freedom of association and collective bargaining consistent with local laws?	0 1 2 3 N/A	
12.4. Do you provide safe and healthy working conditions? Including appropriate PPE when required.	0 1 2 3 N/A	
12.5. Are there policies to ensure operations are carried out with care for the environment and comply with all applicable environmental laws and regulations?	0 1 2 3 N/A	
12.6. Are there policies to ensure your company compliant with the ROHS, REACH, and Conflict Minerals?	0 1 2 3 N/A	
Comments:	Max Points: 18	Total:

13. Logistics Management System	Rating System	Score
13.1. Are there written specifications for purchased materials?	0 1 2 3 N/A	
13.2. Is there a formal procedure or process for handling process or specification changes for purchased material?	0 1 2 3 N/A	
13.3. Is there a formal procedure or process to manage your suppliers that includes corrective action for nonconforming material?	0 1 2 3 N/A	
13.4. Are there procedures and criteria for evaluating and selecting suppliers based on their ability to supply products/services following your organization's requirements?	0 1 2 3 N/A	
13.5. Are there procedures and criteria for identifying and evaluating customer/product requirements before committing to supply product to the customer?	0 1 2 3 N/A	
13.6. Is there an established process to ensure all data critical to company performance routinely backed up at an off-site location?	0 1 2 3 N/A	
Comments:	Max Points: 18	Total:

14. Operations Controls	Rating System	Score
14.1. Do you have a formal manufacturing setup and line clearance process for production?	0 1 2 3 N/A	
14.2. Do you have a documented process for changes that impact specifications, methods, processes, or procedures?	0 1 2 3 N/A	
14.3. Do you perform process capability studies?	0 1 2 3 N/A	
14.4. Do you have written preventive maintenance procedures?	0 1 2 3 N/A	
14.5. Do you utilize material requirements planning (MRP)?	0 1 2 3 N/A	
14.6. Do you have formal contingency plans (or disaster recovery plans) in place for the manufacturing processes?	0 1 2 3 N/A	
Comments:	Max Points: 18	Total:

15. Supplier change notifications.

BVI requires notification of any proposed changes related to supply of product / product related service with a reasonable timeframe, so that it can be assessed for impact by BVI prior to implementation. Any changes should be communicated to BVI at the mailbox address below. A description of the proposed change and processes affected should be defined.

suppliernotification@bvimedical.com

16. Supplier sign off.

By approving this assessment, I certify that these responses best represent the current state of procedures, systems, or practices at the company detailed in section 1.

Print Name……. Job Title……..

Supplier representative signature…….. Date…….

Contact e-mail / phone number……

Please return completed document and requested certification from section 2 to BVI contact Via return e-mail.

BVI Approval - Following sections to be completed by BVI.

17. BVI Supplier Evaluation Rationale		
Initial Supplier Evaluation	Supplier File Maintenance	Supplier Change Evaluation
☐	☐	☐

18. BVI Procurement sign off. (Only applicable for new supplier set up)

By approving this assessment, I certify that all required responses have been provided and all sections have been completed.

BVI Procurement signature…… Print Name……..……

Job Title…….....……
Date……..

3. Contract Review & Document Control	Max Points: 18	Total:
4. Control of Inspection, Measuring & Test Equipment	Max Points: 18	Total:
5. Income Inspection	Max Points: 18	Total:
6. In-Process & Final Inspection	Max Points: 18	Total:
7. Manufacturing & Process Control	Max Points: 18	Total:
8. Packaging, Storage & Shipping	Max Points: 18	Total:
9. Corrective & Preventive Action	Max Points: 18	Total:
10. Training	Max Points: 18	Total:
11. Quality Compliance	Max Points: 21	Total:
12. Labor & Environmental Standards	Max Points: 18	Total:
13. Logistics Management System	Max Points: 18	Total:
14. Operations Controls	Max Points: 18	Total:
Grand Total	Max Points: 219	Total:
Survey performance % (Third party certification is default 100%)	**100%**	%

19. BVI Supplier Classification (Refer to tables in procedure BP7-4-2)			
Is product or service related to product or product manufacturing process? (See scope of supply in section 1.)			
Yes			**No**
Criticality 3	**Criticality 2**	**Criticality 1**	**Criticality 0**
☐	☐	☐	☐

Survey Assessment Results:
☐ Satisfactory ☐ Satisfactory with comments ☐ Unsatisfactory with comments
Comments:

Note:
(1) If Satisfactory with comments, BVI may use the supplier considering additional controls or limitations
(2) If Unsatisfactory, BVI may recommend an onsite Assessment of the Supplier to clarify requirements not met, considering additional controls, limitations, or not consider this supplier for approval.

20. BVI Quality Assurance sign off. (Mandatory Signoff)

By approving this assessment, I certify that these responses have been reviewed and meet the requirements of BVI.

BVI QA signature…… Print Name……..……

Job Title……...……
Date……..