	NUMBER:	V	WI 8.4-1		
	Issue Date:	Revision	Level:	Revision Date:	
DUKE MANUFACTURING PRECISION MEDICAL MANUFACTURING	5-31-17	В		6-21-18	
WORK INSTRUCTION	Document Owner:		Management Representative:		
Supplier Purchase Order Requirements	Jeff Newmark				

Duke Manufacturing/PM Machine recognizes the very important role our Suppliers have in the value we offer our customers. As an extension of our own operations, we rely on our Suppliers to provide material, products, and services which meet all of the requirements of our contracts, applicable specifications, and the quality management requirements outlined herein.

SUPPLIER CODE OF CONDUCT

Suppliers shall ensure operations are being performed in a manner that is appropriate, as it applies to their ethical, legal, environmental, and social responsibilities. Below is a listing of the basic requirements:

Compliance with Local Laws and Regulations

Suppliers must adhere to the laws and regulations in the locality in which they reside. This includes all local, state, and federal laws/regulations in the country of origin.

Compliance with Environmental, Health, and Safety Laws

The Supplier must maintain and operate its manufacturing/production facilities and processes in accordance with local, state, and federal laws/regulations in the country of origin.

Product Safety

In all instances where a product is manufactured to a new design, for a new system, or for a new application, it is important that Supplier and Duke/PM allocate responsibility for assuring that all performance, endurance, maintenance, safety and warning requirements are met. It is preferred that this allocation of responsibility be in writing.

Non-Discrimination

Suppliers shall not discriminate against race, color, sex, religion, age, physical disability, political affiliation, or other defining characteristics as prohibited by local, state, and federal laws/regulations in the country of origin.

Child Labor

Suppliers shall employ workers of minimum legal age in accordance with local,

state, and federal laws/regulations in the country of origin. Child labor laws must be followed.

Forced/Indentured Labor

Suppliers shall not practice the use of forced or indentured labor.

Work Hours/Days

Suppliers shall not exceed the daily and weekly working hours as permitted by local, state, and federal laws/regulations in the country of origin.

Wages and Benefits

Suppliers shall compensate workers in accordance with local, state, and federal laws/regulations in the country of origin. This includes minimum legal wage, overtime wages, and benefits (required by law).

	NUMBER:	V	VI 8.	4-1
	Issue Date:	Revision	Level:	Revision Date:
DUKE MANUFACTURING PRECISION MEDICAL MANUFACTURING	5-31-17	В		6-21-18
WORK INSTRUCTION	Document Owner:		Manag Repres	jement sentative:
Supplier Purchase Order Requirements	Jeff Newmark		Je	off Newmark

Conflict Minerals

No product supplied by Supplier shall contain any mineral that directly or indirectly finances any armed group that has been identified as a perpetrator of human rights abuses, including without limitation those defined as conflict minerals in the rules issued under Section 13(p) of the Securities Exchange Act of 1934.

Ethics

The successful business operation and reputation of Duke/PM is built upon the principals of fair dealing and ethical conduct of our suppliers. Our suppliers are expected to comply with all applicable laws and regulations and expects its employees to conduct business in accordance with the letter, spirit and intent of all relevant laws and to refrain from any illegal, dishonest, or unethical conduct.

Code of Conduct and Policy Enforcement

This policy applies to Suppliers and their sub-tier sources. It is the responsibility of the Supplier to verify and monitor compliance of this code at their operations and sub-tier source operations. **Confidentiality**

The Supplier shall ensure the confidentiality of Duke/PM-contracted products and projects under development, and related product information, as well as intellectual property shared as a result of the working relationship.

COMPLIANCE TO CONTRACTUAL REQUIREMENTS

Upon accepting a Duke/PM contract, the Supplier is responsible for compliance to all contract (e.g.,engineering drawing, specification, purchase order) requirements. All documents, drawings and specifications, regardless of origin, are applicable to the Supplier when specified in the contract or documents referenced in the contract, and are required to be used at all levels of the supply chain.

The Supplier, as the recipient of the contract, is responsible for meeting all requirements, including work performed by the Supplier's sub-tier Suppliers. The Supplier shall include (flow-down) on contracts, to its sub-tier sources, all of the applicable technical and quality requirements contained in the Duke/PM contract.

RISK MANAGEMENT

The Supplier shall establish a risk management program to effectively assess those elements from all aspects of the business that could affect the quality of the products and/or services scheduled for delivery.

	NUMBER:	V	VI 8.	4-1
	Issue Date:	Revision	Level:	Revision Date:
DUKE MANUFACTURING PRECISION MEDICAL MANUFACTURING	5-31-17	В		6-21-18
WORK INSTRUCTION	Document Owner:			jement sentative:
Supplier Purchase Order Requirements	Jeff Newmark		Je	off Newmark

FURNISHED DOCUMENTS

Documents furnished by Duke/PM to the Supplier are furnished solely for the purpose of doing business with Duke/PM. The Supplier is responsible for controlling and maintaining such documents to preclude improper use, loss, damage, alteration and/or deterioration. Unless authorized by Duke/PM, the Supplier may not transmit or furnish any furnished documents, or copies of such documents, to anyone outside the Supplier's business organization except to a sub-tier source used by the Supplier for performance of work on the Duke/PM contract. The Supplier shall flow down this requirement to all sub-tier sources, when such sources will be in receipt of Duke/PM proprietary documents during performance of work for the Supplier.

COUNTERFEIT PARTS

The supplier shall have policy or procedure to cover and apply requirements, practices and methods to mitigate risk of receiving and installing counterfeit parts.

FOREIGN OBJECT DEBRIS (FOD) PREVENTION

The supplier shall establish, document and maintain a FOD system

NON-CONFORMING MATERIAL

Any material found to be non-conforming is to be brought to the attention of the Duke/ PM Purchasing and/ or Quality Departments and be approved in writing by Duke/PM Purchasing and/or Quality Department prior to shipping. If Duke/PM approves the non-conforming to be shipped, the non-conforming parts must be clearly marked so that it is distinguished from compliant material.

DEVIATION TO PURCHASE ORDER REQUIREMENTS

Any deviation to purchase order requirements must be submitted to Duke Purchasing and / or quality department for evaluation.

GENERAL CLAUSES

For change orders, all requirements listed to the original order remain in effect except for changes specified in the body of the change order. Duke Manufacturing reserves the right to return or hold subject to our order, all goods or any part thereof, which are not equal to sample or up to standards set by drawing and/or PO.

SURVEY/AUDIT RIGHTS

Duke Manufacturing/ PM Machine and its customers, and/or regulatory agencies shall have the right to conduct surveys and perform surveillance of the supplier's and sub-suppliers' facilities to

	NUMBER:	V	VI 8.	4-1
	Issue Date:	Revision	Level:	Revision Date:
DUKE MANUFACTURING PRECISION MEDICAL MANUFACTURING	5-31-17	В		6-21-18
WORK INSTRUCTION	Document Owner:		Management Representative:	
Supplier Purchase Order Requirements	Jeff Newmark		Je	eff Newmark

evaluate their capability to comply with the requirements necessary to conform to contractual requirements.

SUPPLIER WRITTEN CHANGE NOTIFICATION

- Supplier must notify Duke Manufacturing/PM Machine if revocation of third party certificate
- Supplier must notify Duke Manufacturing/PM Machine of any change of controlled process status (*i.e. suspension, disapproval or loss of quality system or NADCAP process certification)
- Supplier must notify Duke Manufacturing/ PM Machine when there are significant facility or organizational changes such as company name, location or key personnel.
- Supplier will not subcontract operations without prior written approval of Duke Manufacturing/ PM Machine Purchasing and/or Quality Department

GENERAL QUALITY REQUIREMENTS

- Only approved abrasives are to be used in the manufacturing of these parts. These include silicon carbides, tungsten carbides, boron carbides and diamond. Unless otherwise specified in writing by the buyer, any abrasive leaving surface embedded oxides or nitrides are not permitted, unless a minimum of 0.005" of material is removed by the seller after the operation, which uses non-permitted abrasives. Abrasives that that are not permitted include but are not limited to, Aluminum Oxide, Aluminum Zirconia, Garnet Almandite, and Nitrides. Contact buyer for additional information.
- Duke/PM is a latex free environment and all products manufactured for Duke/PM are to be done so in a Latex free environment, unless otherwise approved by Duke/ PM. Contact Buyer for additional information.

The following clauses will only apply if called out on the Purchase Order:

- 1) **RAW MATERIAL REPORTS AND PAPERWORK** Test and inspection reports as required by the applicable procurement specification must accompany each shipment.
 - a) For raw material shipments, or supplier supplied material, physical and chemical test report certifications (mill certification) shall be supplied with each shipment. Test reports shall be legible and include the material designation, specification and revision letter (material must be certified to the latest revision in effect at the time of manufacturing), results of all specified testing requirements, the mill heat lot number and any other requirements specified on the purchase order.

	NUMBER:	V	VI 8.	4-1
	Issue Date:	Revision	Level:	Revision Date:
DUKE MANUFACTURING PRECISION MEDICAL MANUFACTURING	5-31-17	В		6-21-18
WORK INSTRUCTION	Document Owner:		Management Representative:	
Supplier Purchase Order Requirements	Jeff Newmark		Jeff Newmark	

- b) REQUIRED MATERIAL IS TO BE GE S-400 or NADCAP CERTIFIED Company supplying the raw material is GE S-400 certified or the raw material has been tested by a NADCAP certified Lab and must be stated on the certification for material, or material is capable of being certified by a NADCAP approved lab.
 - If material needs retesting to meet NADCAP certification, if agreed upon by Duke/PM purchasing Duke / PM will have tests performed, with the supplier being responsible if the material fails to meet specification.
 - ii) Supplier is responsible for retesting to meet NADCAP certification.

Any Material being retested must have certified results for all quality requirements of applicable ASTM/AMS per noted specification.

c) RAW MATERIAL POINT OF CERTIFICATION (i.e. the certification laboratory) shall be a laboratory accredited by one of the following organizations and located within the United States, its possessions, Canada or the United Kingdom: NADCAP

A2LA ASTM ISO Guide 25 ISO 17025

- *d)* DFAR Specialty Metals Clause 252-225-7014 and Alternate 1 apply to this Purchase order. Please reference DFAR version Archive 7/21/09 or earlier for Specialty Metals Clause Requirements. Compliance to DFAR's 252.225-7009 (July 2009) in lieu of 252.225.7014 is not permitted on this PO.
- e) Ultrasonic Test per AMS-STD-2154. 100x to Class AA. C of C must include this information
- 2) **MANUFACTURED ITEMS/SUBCONTRACT OPERATIONS** Test and inspection reports as required by the applicable procurement specification must accompany each shipment.
 - a) **CERTIFICATE OF CONFORMANCE** A certificate of conformance shall accompany each shipment of material defined in the purchase order. The certificate of conformance shall be legible and at a minimum include the Duke Manufacturing/ PM Machine purchase order number, part number and Revision (unless otherwise specified on the purchase order the revision must be the latest revision in effect at time of shipment), quantity, material lot number (when purchaser supplied material) and the mill heat number when supplier supplied material. When multiple lots of material are used in completing a shipment, parts shall not be mixed and all material lot numbers or mill heat numbers shall be reported. Parts may be mixed from different material lot numbers if the parts are serialized and it is

	NUMBER:	V	VI 8.	4-1
	Issue Date:	Revision	Level:	Revision Date:
DUKE MANUFACTURING PRECISION MEDICAL MANUFACTURING	5-31-17	В		6-21-18
WORK INSTRUCTION	Document Owner:		Management Representative:	
Supplier Purchase Order Requirements	Jeff Newmark		Je	ff Newmark

reports which material heat lot applies to each serial number. When processing is performed against a work order, parts shall not be mixed and traceability shall be maintained to the work order.

- i) All material and processing must be performed/certified to the latest revision of the drawings and specifications in effect at the time of shipment.
- b) IN PROCESS reports are required. Sample size to be determined by MIL STD 105 and/or ANSI/ASQC Z1.4-1993 or comparable standard. As determined by Duke/ PM Quality Department. A cpk of 1.33 min is required for all Key Characteristics identified by Duke / PM and must be verified by Capability studies, otherwise 100% inspection for those features is required.
- c) FINAL REPORTS are required. Sample size to be determined by MIL STD 105 and/or ANSI/ASQC Z1.4-1993 or comparable standard. As determined by Duke/ PM Quality Department. A cpk of 1.33 min is required for all Key Characteristics identified by Duke / PM and must be verified by Capability studies, otherwise 100% inspection for those features is required.
- d) FIRST ARTICLE Inspection is required on a part representative of the production process to be used in the manufacture of these parts. A copy of the First Article documentation is to accompany the first shipment of parts. Form AS9102 or equivalent is to be used for this documentation. If 12 months has elapsed since the last shipment of this part number, First Article Inspection is again required. A cpk of 1.33 min is required for all Key Characteristics identified by Duke / PM and must be verified by Capability studies, otherwise 100% inspection for those features is required.
- e) **STATISTICAL PROCESS CONTROL** is required during the manufacture of the item(s) for which this clause is called out. SPC shall be in accordance with a plan, approved by the Duke Manufacturing/ PM Machine Quality Department.
- f) SPECIAL PROCESS APPROVAL special processes such as heat treating, welding, electroplating, laser cutting, EDM, ECM, non-destructive testing, etc. require approval by Duke Manufacturing/ PM Machine of the process and the supplier of the process prior to performing the special process. The Certificate of Conformance shall include the specification number and revision of all special processing performed. Special processes, once approved, may not be changed without Duke Manufacturing/ PM Machine approval of the changes.

	NUMBER:	V	VI 8.	4-1
	Issue Date:	Revision	Level:	Revision Date:
DUKE MANUFACTURING PRECISION MEDICAL MANUFACTURING	5-31-17	В		6-21-18
WORK INSTRUCTION	Document Owner:			jement sentative:
Supplier Purchase Order Requirements	Jeff Newmark		Je	eff Newmark

- g) Supplier must be **NADCAP** approved to accept this Purchase Order. Verification required.
- h) Parts (i.e. forgings/ castings) are to be 100% checked with a Nitron Analyzer **(XRF) Gun**, for material composition and certified accordingly.
- 3) **SHIPPING METHOD** Purchased items are to be packaged in a manner as to prevent damage during shipping and handling.
 - a) Ship best way available
 - b) Duke/ PM will pick up
 - c) Supplier to deliver
 - d) Shipments less than 150 lbs. ship UPS, shipments greater than <u>or equal to</u> 150 lbs. ship common carrier as defined on PO.
 - i) Boxes shipped via UPS MUST be packed less than 50 lbs. per box.

4) SHIPPING WINDOW

- a) 7 calendar days early / 0 calendar days late
- b) 5 calendar days early / 0 calendar days late
- c) 2 calendar days early / 0 calendar days late
- d) *Parts shipped before the shipping window may be returned to the supplier at the supplier's expense.

5) SHIPPING TOLERANCE

- a) Shipping Tolerance is +0% 0%
- b) Shipping Tolerance is +5% 0%
- c) Shipping Tolerance is +10% 0%
- d) Unless otherwise specified in purchase order.
- 6) **RECORD RETENTION** Supplier shall retain all records pertaining to material, manufacturing processes, special processes, testing and inspection for
 - a) 15-year minimum. Notify Duke Manufacturing/PM Machine, prior to destruction.
 - b) 7-year minimum. Notify Duke Manufacturing/PM Machine, prior to destruction.
 - c) Life of Product. Notify Duke Manufacturing/PM Machine, prior to destruction.
- 7) **SELLER QUALITY SYSTEM** Supplier must maintain a Quality System that meets, as a minimum, the following requirements
 - a) ISO 9001
 - b) AS 9100

	NUMBER:	V	VI 8.	4-1
	Issue Date:	Revision	Level:	Revision Date:
DUKE MANUFACTURING PRECISION MEDICAL MANUFACTURING	5-31-17	В		6-21-18
WORK INSTRUCTION	Document Owner:		Manag Repres	jement sentative:
Supplier Purchase Order Requirements	Jeff Newmark		Jeff Newmark	

c) ISO 13485

8) ITAR/EAR This Po and all flow down is subject to Export Control Laws. Export-controlled items, as used in this clause, means items subject to the Export Administration Regulations (EAR) (15 CFR parts 730–774) or the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120–130).