



Form Sheet FS7.34

Authorization: *Bill Helie*

Purchasing Terms and Conditions

Revision: 005

Date: 1/20/2017

1. **PURCHASE ORDER AND ACCEPTANCE:** This Purchase Order, together with any documents specifically referenced herein, represents the entire agreement between the parties. The terms and conditions set forth herein and on the face side of the Purchase Order constitute the parties' contractual agreement and supersede any previous oral or written representations, including but not limited to provisions in Seller's quotations, proposals, acknowledgments or other documents. No course of dealing or usage of trade shall be applicable unless expressly incorporated by this Purchase Order. The terms of this Purchase Order may not be varied or modified in any manner, unless in a subsequent writing signed by an authorized representative of Purchaser. Any clerical errors contained on the face side are subject to correction by Purchaser. Seller's written acknowledgment within 10 days of the date of this Purchase Order, commencement of work on the goods or performance of the services subject to this Purchase Order, or shipment of such goods, whichever occurs first, shall be deemed an effective mode of acceptance of this Purchase Order. Any acceptance of this Purchase Order is limited to acceptance of the express terms set forth herein. Any proposal for additional or different terms or any attempt by Seller to vary in any degree any of the terms of this offer in Seller's acceptance or other documents are deemed material and are hereby objected to and rejected, but such proposals shall not operate as a rejection of this offer, unless such variances are in the terms of the description, quantity, price or delivery schedule of the goods or services, and this offer shall be deemed accepted by Seller without said additional or different terms. If this Purchase Order shall be deemed an acceptance of a prior offer by Seller, such acceptance is limited to the express terms set forth herein.

2. **WARRANTY:** In addition to Seller's customary warranties, any express warranties set forth in this Purchase Order, any statutory warranties or any warranties implied by law, Seller expressly warrants that all of the goods or services rendered under this Purchase Order and all other orders: a) do not, and are not claimed to, violate any patent, trademark or copyright, and may be properly imported into the United States or any other country; (b) shall strictly conform with all specifications, drawings, statements on containers or labels, descriptions and samples furnished or specified by Purchaser or Seller; (c) shall be free from defects in design, material and workmanship and shall be new and of the highest quality; (d) Purchaser shall receive title to the goods which is free and clear of any liens, or any other encumbrances; (e) the goods shall be merchantable, safe and fit for Purchaser's intended purposes, which purposes Seller acknowledges are known to it; (f) shall be adequately contained, packaged, marked and labeled; (g) all services performed on behalf of Purchaser shall be performed in a competent, workmanlike manner; (h) the goods shall be manufactured in compliance with all applicable federal, state and local laws, regulations, industry standards or other standards, labeling, transporting, licensing, approval or certification requirements in the United States or any other country where the goods will be sold or used; (i) and Seller has complied with NQA-1, ISO 9001, or equivalent quality program, as applicable, in fulfilling its responsibilities under this Purchase Order and all other orders. These warranties shall survive inspection, test, delivery, acceptance, use and payment by Purchaser and shall inure to the benefit of Purchaser, its successors, assigns, customers and the users of Purchaser's goods and services. These warranties may not be limited or disclaimed. If Purchaser experiences any breaches of the foregoing warranties, Purchaser shall have the right, in addition to exercising all other rights Purchaser may have under the applicable statutes or laws, to take the following actions, at Purchaser's option: (1) retain the defective goods or services in whole or in part with an appropriate adjustment in the price for the goods, (2) require Seller to rework, repair or replace the defective goods or services in whole or in part at Seller's sole expense, including all shipping, transportation and installation costs, (3) replace the defective items with similar items and recover the total cost relating thereto from Seller, including the cost of product recalls, or (4) reject the defective goods or services.

3. **CONTROL OF NONCONFORMING ITEMS:** Prior to offering an item or service for acceptance, the Supplier shall verify that the item or service being furnished complies with the procurement requirements. Nonconformances identified by the Supplier shall be controlled to prevent the delivery of nonconforming items to M.Braun or its customer. Any nonconformance which is not reworked by the Supplier shall be reported to M.Braun on Form Sheet FS7.8, Supplier Deviation Request (SDR), or other M.Braun provided form, prior to delivery to the final destination. Nonconforming items reported via the SDR or other M.Braun provided form shall be segregated and removed from further work or processing pending disposition of the deviation request by M.Braun or its customer. NQA-1 certified, NQA-1 compliant, or 10 CFR Part 50 compliant suppliers shall provide notification to M.Braun, in accordance with 10 CFR Part 21, if the supplier becomes aware of a nonconforming safety related item that was previously delivered. M.Braun will determine if the nonconformance is reportable to the customer and the Nuclear Regulatory Commission (NRC).

4. **WORK PROGRESS AND REJECTIONS:** Purchaser shall have the right (but not the obligation) to review work progress and test all goods, supplies, special tooling, materials and workmanship to the extent practicable at all times and places during the period of manufacture. If any goods delivered or services rendered are defective in material or workmanship or otherwise not in conformity with the requirements of any order, Purchaser shall have the right, notwithstanding payment, any prior inspection or test, custom or usage of trade, either to reject them or to require their correction by and/or at the expense of Seller promptly after notice.

5. **PROPERTY OF PURCHASER:** Unless otherwise agreed in writing, all tooling, dies, special dies, patterns, patents, jigs, gauges, fixtures, drawings, designs, samples, tooling aids, molds and/or any other property that is paid for by Purchaser and/or furnished to Seller by Purchaser and/or made available to Seller by Purchaser for use by Seller in producing any goods or parts covered by any purchase order (the "tooling") is the property of Purchaser or its customer and shall (i) be used exclusively for the benefit of Purchaser; (ii) be used only in filling purchase orders; (iii) remain and be conspicuously identified as Purchaser's property; (iv) be segregated from the property of Seller and others; (v) be removed only upon Purchaser's instructions; (vi) be held at Seller's risk and insured at its expense in a replacement cost amount with loss payable to Purchaser (evidence of insurance to be furnished upon request); (vii) be subject to inspection and removal by Purchaser at any time and for any reason whatsoever; and (viii) be maintained in good condition, at Seller's expense, and not be modified without Purchaser's prior written consent. Seller shall bear the risk of loss of, and damage to, the tooling, normal wear and tear excepted. Seller grants to Purchaser a purchase money security interest in the tooling, any portion thereof, work in progress, raw materials, drawings and other items dedicated to constructing the tooling, and agrees to perform any act and execute any document reasonably necessary to perfect the Purchaser's security interest in the tooling.

6. **PRICE TERMS:** The goods and services will be furnished at the price set forth on the face side of the Purchase Order in U.S. dollars unless otherwise specified. Seller warrants that the price for the goods and services is no less favorable than those currently extended to any other customer for the same or similar goods in similar quantities. Seller agrees to participate in and to provide goods and services in compliance with the requirements of any cost reduction program in which Purchaser is obligated by its customer(s) to participate. Purchaser shall also receive the full benefit of all discounts, premiums and other favorable terms of payment customarily offered by Seller to its customers. In the event Seller reduces its price for the goods and services during the term of this Purchase Order, Seller agrees to reduce the prices to Purchaser correspondingly. Seller warrants that the prices in this Purchase Order shall be complete, and no additional charges of any type shall be added without Purchaser's express written consent.



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7. CONFIDENTIALITY: Seller agrees not to disclose to third parties any information regarding Purchaser or its business or its customers, including the existence and terms of any purchase order, or use such information itself for any purpose other than performing this order, without Purchaser's written prior approval. This paragraph shall apply to drawings, specifications and any other documents prepared by Seller for Purchaser in connection with any purchase order.

8. DELIVERY, TRANSPORTATION AND PAYMENT: Time is of the essence. Delivery must be effected within the time specified in this Purchase Order. Any costs associated with the receipt of late deliveries or nonconforming goods and services under any purchase order may be charged back to Seller. If delivery is not timely made, Purchaser may, in addition to its other rights and remedies, direct Seller to make expedited routing at Seller's expense. The goods shall be properly packed, marked, loaded and shipped as required by this Purchase Order and by the transporting carrier. Unless Purchaser instructs otherwise, the goods shall be shipped in a manner that permits the lowest transportation rates to apply and adequately protects the quality of the goods. Seller shall reimburse Purchaser for all expenses, including damage to the goods, incurred due to improper packing, marking, loading or routing. The risk of loss or damage in transit shall be upon the Seller, except where shipment is by Purchaser's vehicle, in which case the risk of loss or damage shall pass to Purchaser upon completion of loading. Seller shall not procure, produce or ship any goods unless authorized in writing by Purchaser or as necessary to meet specific delivery dates. Shipments in excess of those authorized by Purchaser may be returned to Seller at Seller's expense. Purchaser may change shipping schedules or direct temporary suspension of such scheduled shipments. Upon submission of proper invoices, Purchaser shall process such invoices for payment. Payment may be withheld, or portions deducted, charged-back, or set-off, for any claims that Purchaser may have against Seller, or its related or affiliated companies. All cash discounts shall be computed from the date of receipt by Purchaser of a final invoice or receipt of the goods and services, whichever occurs later. Cash discounts shall be based on the full amount of invoice, less freight charges and taxes if itemized separately on the invoice.

9. DOCUMENTATION: Packing slips (which shall accompany the goods), shipping documents and memos, ASN documents, and bills of lading shall show the purchase order number, vendor, and item and reference numbers. Shipping documents shall be mailed on shipment date and must include the ASN, SID, Bill of Lading or Packing Slip numbers relating to each shipment. Value of the goods shall not be declared on shipments F.O.B. point of origin. For each international shipment, Seller shall include a customs valuation invoice with a master packing slip and shall furnish all other required export/import documents. Export and trade credits shall belong to Purchaser. Seller shall furnish (i) all documents required to obtain export credits and customs drawbacks; (ii) certificates of origin of the materials and goods supplied and the value added in each country; (iii) all NAFTA, AALA and other related documents; (iv) all required export licenses or authorizations; and (v) any other documents requested by Purchaser or any of its customers. Seller warrants that the contents of such documents shall be true and accurate. Seller shall indemnify Purchaser for any damages, including but not limited to duties, interest and penalties, arising from a false or inaccurate statement.

10. INTELLECTUAL PROPERTY: Upon notice and demand from Purchaser, Seller agrees to promptly assume full responsibility for defense of any suit, proceeding or claim which may be brought against any of the Indemnities as defined in the Indemnification paragraph below, in the United States or any other country, for alleged patent, copyright, trademark or industrial rights infringement, as well as for any alleged unfair competition resulting from similarity in design, trademark or appearance of goods delivered or services rendered under this Purchase Order. Seller further agrees to indemnify and hold harmless each of the Indemnities from and against any and all losses, royalties, profits, damages and expenses (including court costs and reasonable attorney's fees) resulting from any such suit, proceeding or claim, including any settlement. Purchaser has the right to be represented by and actively participate through its own counsel in any such suit, proceeding or claim. Seller agrees that Purchaser shall have a nonexclusive, royalty free, irrevocable license to make, repair, rebuild and relocate the goods (or to have the goods made, repaired, rebuilt and relocated). All inventions (whether or not patentable), designs, drawings, copyrights, know-how, data and other information developed by Seller specifically in response to any purchase order shall be furnished to Purchaser without restriction on use or disclosure, and Purchaser shall have a nonexclusive, royalty free, irrevocable license, with a right to sublicense, to use such inventions, designs, drawings, copyrights, know-how, data and other information.

11. US C-TPAT U.S. Customs Service's Customs Trade Partnership Against Terrorism): For Seller's goods to be imported in the United States, Seller shall accept, implement and comply with all applicable recommendations or requirements of the United States Customs Service's Customs Trade Partnership Against Terrorism ("C-TPAT") initiative (for information go to <http://www.customs.ustreas.gov/enforcem/entxt.htm>). At Buyer's or the Customs Service's request, Seller shall certify in writing its acceptance, implementation and compliance with the C-TPAT and any accompanying recommendations and guidelines. Seller shall indemnify and hold Buyer harmless from and against any liability, claims, demands or expenses (including attorney's or other professional fees) arising from or relating to Seller's not accepting, implementing or complying with C-TPAT.

12. TERMINATION AND CHANGE:

A. Purchaser may terminate this Purchase Order, or any term or condition under this Purchase Order for cause in the event of any breach by the Seller of this Purchase Order. The following constitute "for cause" terminations of this Purchase Order: (i) late deliveries; (ii) deliveries of goods and services that are defective or that do not conform to this Purchase Order; (iii) breach by Seller of the terms and conditions of this Purchase Order; (iv) failure upon request to provide Purchaser with reasonable assurances of future performance; (v) insolvency of Seller; (vi) the filing of an involuntary petition of bankruptcy against Seller or a voluntary petition by Seller; (vii) the execution by Seller of an assignment for the benefit of creditors; (viii) the commencement of any receivership or like proceedings relating to Seller's assets; or (ix) if the Seller is a party to a merger, consolidation or other extraordinary corporate transaction in which it is not the surviving entity. In the event of termination of this Purchase Order by Purchaser for cause, Purchaser shall not be liable to Seller for any amount, and Seller shall be liable to Purchaser for all damages, direct or indirect, consequential and incidental, sustained by reason of the default which gave rise to the termination, including, but not limited to, excess costs incurred by Purchaser as a result of obtaining the goods and services from another source.

B. Purchaser reserves the right to terminate this Purchase Order or any term or condition under this Purchase Order, in whole or in part, at any time or from time to time, for its sole convenience. In the event of such termination, Seller shall immediately stop all work and cause all of its suppliers and subcontractors to cease work on the portion of this Purchase Order so terminated. Upon approval by Purchaser, as Seller's sole compensation for the Purchaser's termination of this Purchase Order or portions thereof, Seller shall be paid a reasonable termination charge consisting solely of an amount equal to the purchase price of the finished goods and services accepted by Purchaser, as set forth in this Purchase Order, and documented costs to Seller of work in process and raw material allocable to the work to be performed pursuant to this Purchase Order, previously authorized by Seller, but in no event shall the amount payable hereunder exceed the purchase price of the



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finished goods and services which would have resulted from the completion of such work in process and raw materials. Seller will have no obligation to Purchaser upon such termination to pay for goods, work in process or raw materials which are in Seller's standard stock or inventory or which are readily marketable. Within 30 days after receipt of a termination notice, Seller shall submit its claim. Purchaser reserves the right to verify the claim by auditing all relevant records. Seller shall not be paid for any work performed after receipt of the notice of termination, nor for any costs incurred by Seller's suppliers or subcontractors. In no event shall Purchaser be liable for loss of profits, overhead, general and administrative charges, product development and engineering costs, interest, finance or hedging costs, unamortized depreciation costs, or any other direct or indirect cancellation charges. Seller shall transfer title and deliver to Purchaser, if so requested by Purchaser, all undelivered goods, work in process, or raw materials paid for by Purchaser as provided above.

C. Purchaser shall have the right to make any changes, additions or alterations in the items, quantities, destinations, specifications, drawings, designs or delivery schedules. The parties will undertake to negotiate an appropriate adjustment in price and terms where the Seller's direct costs are materially affected by such changes. Any request by Seller for an adjustment in price or terms must be made within 30 days of any such change. All changes and adjustments, if any, must be in writing and signed by a duly authorized representative of Purchaser.

13. INSURANCE: Seller shall maintain insurance in amounts acceptable to Purchaser, naming Purchaser as an additional insured, and covering general liability, public liability, product liability, product recall, completed operations, contractor's liability, Worker's Compensation, and employer's liability insurance as will adequately protect Purchaser against such damages, liabilities, claims, losses and expenses (including attorney's fees). Seller agrees to submit certificates of insurance, evidencing its insurance coverage when requested by Purchaser.

14. INDEMNIFICATION: To the full extent permitted by applicable law and independent of any insurance, Seller agrees to indemnify, hold harmless and defend Purchaser and its affiliated companies, their directors, officers, employees, successors, assigns, agents and customers ("Indemnitees") from and against any and all damages, losses, claims, liabilities, expenses (including but not limited to court costs and attorney fees, settlements and judgments, punitive and exemplary damages, economic loss and loss of profits, and fines and penalties) arising out of or resulting in any way from any defect in the goods delivered or services rendered under this Purchase Order; or any injury to any person (including death) or damage to property caused by Seller, its employees, agents, or subcontractors ("Seller and its representatives"); or any act or omission of Seller and its representatives pursuant to this Purchase Order or in connection with their performance of any work for, and/or on the premises of Purchaser, even if caused by or resulting from negligence of Purchaser; or Seller's breach and/or Purchaser's termination of this Purchase Order. This indemnification obligation shall be in addition to Seller's warranty obligations.

15. RIGHTS, REMEDIES AND CONSTRUCTION: Purchaser's rights and remedies shall be cumulative and in addition to any other rights or remedies provided by law or equity. A waiver by Purchaser of any right or remedy shall not affect any rights or remedies subsequently arising under the same or similar clauses. Any attempt on the part of Seller to limit Purchaser's remedies or the amount and types of damages it may seek shall be null and void. The failure of the Purchaser to insist upon the performance of any term or condition of this Purchase Order, or to exercise any right hereunder shall not be construed as a waiver of the future performance of any such term or condition or the exercise in the future of any such right. If any term of this Purchase Order is invalid or unenforceable under any statute, regulation, ordinance, executive order or other rule of law, such term shall be deemed reformed or deleted, but only to the extent necessary to comply with such statute, regulation, ordinance, order or rule, and the remaining provisions of this Purchase Order shall remain in full force and effect.

16. DELAYS AND LABOR DISPUTES: Whenever Seller has knowledge of any actual or potential cause or event which delays or threatens to delay the timely performance of any purchase order, Seller shall immediately give Purchaser written notice thereof, including all relevant information. Seller shall notify Purchaser in writing of any actual or potential labor dispute delaying or threatening to delay timely performance of this Purchase Order. Seller shall notify Purchaser in writing 6 months in advance of the expiration of any current labor contracts. Seller shall deliver a supply of finished goods at least 30 days prior to the expiration of any such labor contract, in quantities and for storage at sites designated by Purchaser.

17. FEDERAL CONTRACTS; FAIR LABOR STANDARDS: To the extent required by law, the following clauses relating to contracts with the U.S. Government are incorporated into and made applicable to all orders: (i) the Equal Opportunity clause, 41 CFR 60-1.4; (ii) the Affirmative Action for Disabled Veterans & Veterans of the Vietnam Era clause, 41 CFR 60-250.4; and (iii) the Affirmative Action for Handicapped Workers clause, 41 CFR 60-741.4 Seller hereby agrees to comply with all applicable requirements of Sections 6, 7 and 12 of the Fair Labor Standards Act, 29 USC §§ 201 et seq. in the performance of work under any purchase order, and with all applicable regulations and orders issued under Section 14 thereof.

18. TOXIC SUBSTANCES; OSHA: Seller hereby warrants and represents that it has complied with all applicable laws, rules and regulations issued under the Toxic Substance Control Act, 15 USC §§ 2601 et seq., and will defend and indemnify Purchaser from all claims, liabilities, losses, and damages arising out of any failure to so comply. To the extent that any of the goods covered by any order are to be used by Purchaser or its customers in connection with manufacturing or assembly operations, including any activities incidental thereto, Seller certifies that the goods comply with all applicable rules, regulations and standards issued under the Occupational Safety & Health Act, 29 USC §§ 651 et seq., and Seller agrees to defend and indemnify Purchaser and its customers from all claims, liabilities, losses and damages arising out of any failure of the goods to so comply. Prior to shipment, Seller will furnish applicable Material Safety Data Sheets as well as information on the safe use and hazards associated with use of the goods.

19. LIMITATION ON PURCHASER'S LIABILITY: In no event shall Purchaser be liable to Seller for anticipated profits or for incidental or consequential damages. Purchaser's liability for a claim of any kind for any loss or damage arising out of or in connection with or resulting from this Purchase Order, or from any performance or breach, shall in no case exceed the price allocable to the goods or services, which directly gives rise to the claim.

20. TAXES: Unless prohibited by law, the Seller shall pay all federal, state or local tax, transportation tax, or other tax, including but not limited to customs duties and tariffs, which is required to be imposed upon the goods and services ordered, or by reason of their sale or delivery. All order prices shall be deemed to have included all such taxes.

21. FORCE MAJEURE: Neither party shall be liable for defaults due to acts of God or the public enemy, acts or demands of any government or any government agency, strikes, fires, floods, accidents, or other unforeseeable causes beyond its control and not due to its fault or negligence; provided, however, Force Majeure



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shall not include any labor problems or strikes relating to the workforce of Seller or its suppliers or subcontractors or any commercial circumstances affecting pricing or availability of any goods or raw materials furnished by Seller or its suppliers or subcontractors. Each party shall notify the other in writing of the cause of such delay within 5 days after the beginning thereof. During the period of such delay or failure to perform by Seller, Purchaser, at its option may purchase goods and services from other sources and reduce its schedules to Seller by such quantities, without liability to Seller or have Seller provide the goods and services from other sources in quantities and at times requested by Purchaser and at the price set forth in this Purchase Order, if requested by the Purchaser. Seller shall within 10 days of Purchaser's request for adequate assurances provide Seller's assurances that the delay shall not exceed 30 days. If the delay lasts more than 30 days or Seller does not provide adequate assurance that the delay will cease within 30 days, Purchaser may immediately cancel the Purchase Order without liability as set forth in Paragraph 11.A. above.

22. ASSIGNMENT: This Purchase Order is issued to the Seller in reliance upon the Seller's personal performance of the duties imposed. The Seller agrees not to, in whole or in part, assign this Purchase Order or delegate the performance of its duties without the written consent of the Purchaser. Any such assignment or delegation without the previous written consent of the Purchaser, at the option of the Purchaser, shall effect a cancellation of this Purchase Order. Any consent by the Purchaser to an assignment shall not be deemed to waive Purchaser's right to recoupment from Seller and/or its assigns for any claim arising out of this Purchase Order.

23. RELATIONSHIP OF PARTIES: Seller and Purchaser are independent contracting parties and nothing in this Purchase Order shall make either party the agent or legal representative of the other for any purpose whatsoever, nor does it grant either party any authority to assume or to create any obligation on behalf of or in the name of the other party.

24. LAW/FORUM: The rights and obligations of the parties and the terms identified herein and elsewhere in any existing purchase order shall be governed by and construed in accordance with the domestic laws of the State of New Hampshire. Any legal or equitable actions arising out of or relating to any terms identified herein or elsewhere in any purchase order shall be brought only in federal or state court in New Hampshire. Seller and Purchaser agree that such court shall have in personal jurisdiction over the parties.

25. CUSTOMER REQUIREMENTS; SERVICE PARTS: To the extent that this Purchase Order or any other order covers goods which are parts, components, items, tooling and services being supplied to or for the benefit of any customer of Purchaser, Seller acknowledges and agrees that such goods and services must be in compliance with all of the applicable requirements, specifications, standards, pricing requirements (even if such pricing differs from the Purchase order or order price), audit standards, and terms and conditions for such goods and services which are set forth in the customer's purchase documents. Seller shall provide service parts to Purchaser and/or its customer(s) for any goods and parts furnished under any purchase order based upon the customer's service requirements.

26. PROMPTNESS: Time is of the essence for the performance of Seller's obligations created under any and all purchase orders.

27. CONSULTING: To the extent this is a Purchase Order which includes services or consulting services, Seller hereby assigns to Purchaser all rights, title and interest in and to any and all ideas, inventions, improvements, materials, copyrightable material, drawings, documents or the like, conceived or made by Seller as a result of or relating to work done or services performed for Purchaser pursuant to this Purchase Order. Such assignment includes all proprietary rights appurtenant thereto, and Seller will execute any documents necessary to confirm such assignment.

28. RIGHT OF ACCESS: Buyer and its customers shall have the right of access at any reasonable time to examine all work or products supplied under this Purchase Order, all relevant documents, records, materials, equipment, tooling and goods in the possession or under the control of Seller relating to any of Seller's obligations under this Purchase Order or any other purchase order. Seller agrees to cooperate in any such audit request by the Buyer. Right of access to any and all Supplier or lower-tier Supplier facilities or work locations shall be afforded to the authorized Contractor representative at all reasonable times.

29. SPARES AND REPLACEMENT PARTS: The Supplier shall submit a Recommended Spares and Replacement Parts List(s) if required by this Purchase Order. The list(s) shall provide the name and address of the original supplier of each spare and/or replacement part, the part's drawing and/or specification identity (including change or revision information), the appropriate technical and QA data, the part's estimated procurement lead time, and any quantity price breaks.

30. SUSPECT/ COUNTERFEIT ITEMS: Unless otherwise specified, items required by this Purchase Order shall be procured directly from the original manufacturer or an authorized OEM master distributor. Items delivered under this Purchase Order will be inspected by M.Braun for indications of suspect or counterfeit conditions per DOE O 414.1D, Quality Assurance, and DOE G 414.1-3, Suspect/Counterfeit Items Guide for Use with 10 CFR 830, Subpart A, Quality Assurance Requirements. Detection by M.Braun of any suspect or counterfeit item leading to evidence of deliberate misrepresentation of any supplied item, may result in an investigation into the validity of certification, fraud, and/or forgery.