

# Supplier Manual

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## **PURCHASING POLICIES AND PROCEDURES**

#### A.01 General

It is the intent of the Purchasing Department to establish and adhere to procedures for the procurement of material and services that are consistent throughout Phillips-Medisize, LLC and to strive to provide its customers with quality and service second to none through continuous improvement.

It is the responsibility of each person involved in the procurement process to understand the policies, upon which these procedures are based, and the meaning and intent of the procedures. It is also the responsibility of those individuals granted the purchasing authority to follow and enforce the established set procedures and policies.

Contact the Purchasing Department for any clarification of policy or procedure.

The fundamental purpose of these procedures is not to restrict the effectiveness of the individuals involved in procurement, but to provide a foundation for effective, consistent, and complete consideration of aspects involved. The expected results will be a positive, professional relationship between Phillips-Medisize, LLC and its suppliers.

## A.02 Scope

The purchasing function involves the procurement of material, supplies, equipment and services at the lowest possible total cost; consistent with the quality needed for the production of product, which meets the high standards of Phillips-Medisize, LLC.

This document provides guidelines for use in procurement activities. It is designed to identify common policies to be observed throughout Phillips-Medisize, LLC facilities.

## A.03 Objectives

The overall goal is to maintain, at all times, and under all conditions, a continuous supply of goods and services necessary to support production requirements. Purchasing gives prime consideration to the company's interest while seeking to maintain and further long term mutually profitable, ethical supplier relationships.

Those segments of this responsibility are:

- 1. Ensure the uninterrupted flow of production by obtaining and ensuring delivery of acceptable quality of goods and services at the right time and place.
- 2. Develop reliable alternate sources of supply to meet company requirements where justified.
- 3. Treat all prices and technical information submitted by suppliers as confidential in order to preserve a good business reputation and obtain competitive prices.
- 4. Comply in all respects with the antitrust laws and with all other applicable laws.
- 5. Purchase materials and services for the company's use at the maximum end use value per dollars spent within the required specifications.
- 6. Resolve complaints on all purchased goods.
- 7. Provide guidance for the management of inventories of purchased goods.
- 8. Provide guidance in the standardization of materials, supplies, equipment, service and procedures.
- 9. Dispose of, to the best advantage, all material and equipment declared to be surplus or obsolete.
- 10. To subscribe to and work for honesty and truth in buying and selling, and denounce all forms of bribery.
- 11. Avoid the intent and appearance of unethical and comprising practice in relationships, actions, and communications.

# A.04 Delegation of Authority

Phillips-Medisize, LLC grants the Purchasing Department the authority and responsibility for the procurement of all material, equipment, supplies, and services necessary to support the company's needs.

Within this authority, the Purchasing Department, in conjunction with the Facility Manager, may delegate this authority to specific agents who have the responsibility of some of the procurement duties. Such delegation of authority must be written into facility work instructions.

Please Note: All Suppliers must notify the Phillips-Medisize, LLC Purchasing department when scheduling an appointment to visit a Phillips-Medisize, LLC Facility.

## A.05 Diversified Sourcing Statement

Phillips-Medisize, LLC's intent is to support diversified purchasing by actively and aggressively pursuing quotations from Diversified Suppliers. Our objective is to identify material, component and service suppliers that will provide a competitive advantage (lower cost, engineering capability, quality materials, etc.), and support our desire to achieve optimal value for our customers and Phillips-Medisize, LLC.

The emphasis will be on identifying Diversified Suppliers who are best qualified to support our needs and standards. Opportunities will be provided to Diversified Suppliers as capable suppliers are identified.

## A.06 Equal Opportunity and Affirmative Action

Phillips-Medisize, LLC, through its responsible managers, recruits, hires, advances, trains and promotes in all job titles without regard to race, color, religion, sex, national origin, age, disability or veteran status.

As a federal contractor/subcontractor, Phillips-Medisize, LLC is subject to the requirements of: Executive Order 11246, as amended (Equal Employment Opportunity); including, but not limited to, Executive Order 13665; Section 2012 of the Vietnam Era Veterans' Readjustment Assistance Act of 1974, Section 503 of the Rehabilitation Act of 1973 and Executive Order 13201 (Notice of Employee Rights Concerning Payment of Union Dues).

It is a Phillips-Medisize, LLC requirement that all applicable suppliers, subcontractors and service providers to Phillips-Medisize, LLC adhere and fully comply under the foregoing executive orders (clauses incorporated by reference).

- A. EQUAL OPPORTUNITY CLAUSE (applicable to federal contractors and sub-contractors, with orders amounting to \$10,000 or more; 41 CFR 60-1.4). Supplier is aware and fully informed of its responsibilities under Executive Order 11246 and agrees to be bound by its provisions. (Reference to Executive Order 11246 includes all amendments.)
- B. AFFIRMATIVE ACTION COMPLIANCE PROGRAM (applicable to federal contractors and subcontractors, with orders amounting to \$50,000 or more, provided contractor/supplier has 50 or more employees). Supplier certifies to Phillips-Medisize, LLC and to the United States government that since Phillips-Medisize, LLC is a federal contractor, Supplier will, if appropriate: (a) file with the appropriate federal agency a complete and accurate report on Standard Form 100 (EEO-1) within 30 days after the signing of this certificate (unless such a report has been filed in the last 12 months), and continue to file such reports annually, on or before September 30, or as otherwise provided by law or regulation; and (b) develop and maintain a written affirmative action compliance program in accordance with the regulations of the Office of Federal Contract Compliance Programs promulgated under Executive Order 11246, as amended.

# A.06 Equal Opportunity and Affirmative Action, continued...

- C. EMPLOYMENT OF THE DISABLED (Executive Order 11758, applicable to federal contractors and sub-contractors, with orders amounting to \$10,000 or more). Supplier acknowledges that if applicable, it is bound by the Affirmative Action for Disabled Workers Clause set forth in Section 60-741.4 of Title 41 C.F.R., promulgated under Section 503 of the Rehabilitation Act of 1973 and that the clause is incorporated by reference into this Certificate of Compliance.
- D. EMPLOYMENT OF QUALIFIED COVERED VETERANS (applicable to federal contractors and subcontractors, with orders amounting to \$100,000 or more). Supplier acknowledges that if applicable, it is bound by the Affirmative Action and Nondiscrimination Obligations of Contractors and Subcontractors Regarding Disabled Veterans, Recently Separated Veterans, Other Protected Veterans, and Armed Forces Service Medal Veterans, as set forth in Section 60-300 of Title 41 C.F.R., promulgated under the Vietnam Era Veterans' Readjustment Assistance Act of 1974, as amended, and that the clause is incorporated by reference into this Certificate of Compliance.
- E. NOTICE OF EMPLOYEE RIGHTS CONCERNING PAYMENT OF UNION DUES (applicable to federal contractors and sub-contractors, with orders amounting to \$100,000 or more). Under Federal law as set forth by Title 29, CFR 470, employees cannot be required to join a union or maintain membership in a union to retain their jobs. Employees who are subject to a union security clause and choose not to be union members may object to the use of their compulsory union dues and fees for union expenditures that are not related to representational activities, such as collective bargaining, contract administration and grievance adjustment. Employees who object to paying for non-representational activities may be entitled to a refund and appropriate reduction of future payments.

#### **PURCHASE ORDER TERMS AND CONDITIONS**

- 1. Acceptance, Modification, Conflict. This Purchase Order ("Order") when accepted shall constitute a contract upon the terms and conditions stated on the face and reverse sides of this Order. Acceptance shall occur either by acknowledgment or by commencement of performance by Seller, whichever event occurs first. Any addition to or other modification in these terms and conditions or to quantities, prices, or deliveries contained in any acknowledgment, invoice, other form or communication from seller is hereby objected to and rejected notwithstanding Phillips-Medisize, LLC acceptance of delivery or payment for goods and services. If any of Seller's prior proposals, quotations, or writings are in conflict with the terms of this Order, the terms or this Order shall govern. Phillips-Medisize recognizes that Seller may, for operating convenience or otherwise, utilize its own form of acknowledgment or confirmation of sale in accepting this Order. In such event, any provisions, terms, or conditions in such form, which modify, conflict with, contradict, or add to any provision, term, or condition of this Order shall be deemed to be waived by Seller unless expressly accepted in writing by Phillips-Medisize notwithstanding Phillips-Medisize's acceptance of y or payment for goods or services.
- 2. Changes. Phillips-Medisize shall have the right at any time to make changes in drawings, designs, specifications, materials, packaging, time and place of delivery, and method of transportation. If any such change causes an increase or decrease in the cost, or the time required for the performance, an equitable adjustment shall be made and this Order shall be accordingly modified n writing. Seller agrees to accept any and all such changes, subject to this paragraph.
- 3. Termination for Convenience of Phillips-Medisize. Phillips-Medisize reserves the right to terminate this Order or any part hereof for its sole convenience. In the event of such termination, Seller shall immediately stop all work and shall immediately cause its suppliers or subcontractors to cease work. Seller shall be paid a reasonable termination charge reflecting the percentage of the work performed prior to the notice of termination, plus actual direct cost resulting from termination. Seller shall not be paid for any work done after receipt of the notice of termination, except that work necessary to effect termination, nor for any cost incurred by Seller's suppliers or subcontractors which Seller reasonably could have avoided.
- 4. Termination for Cause. Phillips-Medisize may also terminate this Order or any part hereof for cause in the event of any default by Seller, or if Seller fails to comply with any of the terms and conditions of this Order. In the event of termination for cause, Phillips-Medisize shall not incur any liability for such termination and without prejudice to any other remedy Phillips-Medisize may have, Seller shall be liable to Phillips-Medisize for any and all damages sustained by reason of the default.
- 5. Delivery, Performance, and Inspection. The delivery or completion date shall be as stated on the face side of this Order, and if not so stated, then the delivery or completion date acknowledged by Phillips-Medisize shall govern. TIME IS OF THE ESSENCE with respect to Seller's obligations hereunder, and if delivery of items or rendering of service is not completed by the time promised, Phillips-Medisize reserves the right, in addition to its other rights, to return goods or cancel all or part of this Order and charge Seller with all costs, expenses, and damages associated with Seller's failure. Unless stated otherwise in this Order, goods shall be delivered F.O.B. destination designated by Phillips-Medisize. Phillips-Medisize may return or store at Seller's expense any items delivered more than thirty (30) calendar days in advance of the delivery date specified for such items. Goods will be subject to inspection and approval at a reasonable time after delivery and if found to be defective or not in conformity with specifications will be returned at Seller's expense. "Reasonable time" shall take into account goods which defects of nonconformity are not apparent on examination and therefore require a longer period. Nothing in this Order shall relieve Seller from the obligations of testing, inspection, and quality control.
- 6. Risk of Loss. Seller shall bear all risk of loss on items covered by this Order until final acceptance at destination specified on this Order, except loss occasioned by negligence of Phillips-Medisize. m "F.O.B." shall not vary the provisions of this paragraph.
- 7. Pricing. Seller warrants that the prices charged for the items covered by this Order will be as low as the lowest prices charged by Seller to any other customers purchasing similar items in the same or smaller quantities and under like circumstances. Also, the price which Seller charges in filling this Order shall not be higher than the price last charged or quoted to Phillips-Medisize for such items (if there has been a charge or quote previously made to Phillips-Medisize) unless Phillips-Medisize expressly agrees to such higher price. If Phillips-Medisize has set forth a price on the face side of this Order, such price shall control. Except as is otherwise provided on the face side of this Order, the contract price includes all applicable federal, state, and local taxes.
- 8. Payment Terms. Unless otherwise stated on the face side of this Order, payment shall be made within sixty (60) days after delivery, except Seller may offer cash discounts. The time during which discounts for payment of invoices is allowed shall not begin to run until the date goods are received by Phillips-Medisize, notwithstanding an earlier date of invoice.
- 9. Warranties. Seller warrants that all goods will be free from defects of material or workmanship, will be of good quality, and fit and sufficient for the purposes intended, and will conform strictly to any specifications, drawings, or samples which may be specified or furnished by Phillips-Medisize. Seller warrants that it will have good title to all goods, free and clear of all liens, encumbrances, and other obligations and will transfer such good and clear title to Phillips-Medisize. These warranties shall survive acceptance and payment and shall run to Phillips-Medisize, its successors, assigns, customers, and the user of the goods and shall not be deemed to be the exclusive warranties. Without prejudicing any other rights or remedies which Phillips-Medisize may have, if any items covered by this Order are defective or otherwise not in conformity with the requirements of this Order, Phillips-Medisize may by written notice to Seller (a) rescind this Order as to such items, (b) accept such items at an equitable reduction in price, or (c) reject such items and require the delivery of replacements. Deliveries of replacements shall be accompanied by a written notice specifying that such items are replacements
- 10. Indemnification. Seller shall defend, indemnify, and hold Phillips-Medisize harmless against any and all damages, claims, costs, and expenses (including attorney fees) arising out of or resulting from the goods or services purchased hereunder, or from any act or omission of Seller, its agents, employees, or subcontractors. If this Order involves the performance of services by Seller on Phillips-Medisize's premises, Seller shall pay and discharge all liabilities of Seller to all employees of Seller, its agents and subcontractors including, but not limited

- to, liability for personal injury or death arising out of or resulting from the performance of such services. Without prejudice to any other remedy which Phillips-Medisize may have. Seller shall be responsible for and bear the expense of, any necessary correction, (including any repair, replacement, or recall) due to faulty workmanship or materials, or due to faulty design, unless such design was supplied by Phillips-Medisize.
- 11. Insurance. Seller shall have (and shall furnish to Phillips-Medisize's satisfactory evidence thereof upon request) insurance with minimum limits as follows: worker's compensation insurance as required by law: bodily injury and property damage public liability insurance of not less than \$1 million per occurrence, including contractual liability coverage: and automobile bodily injury liability insurance of no less than \$250,000 per person, and \$500,000 per accident, and property damage liability of \$500,000 per accident, or with such other limits as Phillips-Medisize may specify in this Order or from time to time in writing.
- 12. Patents; Property Rights. Seller shall indemnify, hold harmless and, if requested by Phillips-Medisize, defend Phillips-Medisize against any and all claims, including but not limited to claims of Phillips-Medisize's customers, that goods or services sold hereunder infringe any United States or foreign letters patent, copyright, trademark, or any other rights and against any and all claims of unfair competition or trade secret violations provided Phillips-Medisize gives Seller reasonable notice in writing of any action or proceeding and, at Seller's expense, gives Seller necessary information, assistance, and authority to do so; and Seller shall defend, indemnify, and hold Phillips-Medisize and its customers harmless against any and all expenses, losses, royalties, profits, damages, and costs (including attorney fees) resulting from any such action or proceedings, including any settlement. Phillips-Medisize may be represented by and actively participate through its own counsel in any such suit or proceeding if it so desires. All copyrightable material arising out of anything done pursuant to this Order shall constitute works made for hire and Seller agrees to take appropriate action to assign such rights to Phillips-Medisize.
- 13. Proprietary Information; Confidentiality; Advertising. Seller shall consider all information furnished by Phillips-Medisize or any other person acting on behalf of Phillips-Medisize to be confidential and shall not disclose any such information to any other person, or use such information itself for any purpose other than performing this Order unless Seller first obtains written permission from Phillips-Medisize. All such information in tangible form, including drawings, samples, models, specifications, or other documents prepared by Seller for Phillips-Medisize shall be returned to Phillips-Medisize promptly upon request. Seller shall not advertise or publish the fact that Phillips-Medisize has contracted to purchase goods or services from Seller, nor shall information relating to this Order be disclosed without Phillips-Medisize's written permission. Unless otherwise agreed to in writing, no information disclosed by Seller to Phillips-Medisize shall be deemed secret or confidential and Seller shall have no rights against Phillips-Medisize with respect thereto.
- 14. Assignment, Successors, and Subcontracting. Without the prior written approval of Phillips-Medisize, Seller shall not (i) assign or subcontract this Order or (ii) delegate its performance under this Order. Subject to the provisions in this paragraph, this Order shall be binding upon and shall insure to the benefit of the respective parties hereto and the permitted successors and permitted assigns of the parties hereto.
- 15. Shipment Instructions. Each shipment of goods under this Order shall be covered by a separate itemized invoice showing the date of shipment and all other relevant information. At the time of such shipment, Seller shall mail such itemized invoice and shall forward with each shipment a shipping memorandum stating the order number, describing the transaction and providing all other relevant information, and a bill of lading. Partial shipments must be identified as such on shipping memoranda and invoices and be marked "Partial" Completed shipments must be marked as "Final".
- 16. Compliance with Applicable Legal Standards. Seller further warrants that all goods provided and all services performed hereunder will be in compliance with all requirements of the Federal Fair Labor Standards Act, as amended. Seller also warrants that applicable provisions of the Occupational Safety and Health Act of 1970, as amended, and the Rules, Regulations and Standards issued thereunder, applicable provisions of Executive Order No. 11246, as amended, and the Rules and Regulations issued thereunder, applicable Rules and Regulations promulgated pursuant to the Rehabilitation Act of 1973 and the Vietnam Era Readjustment Assistance Act of 1974, and applicable provisions of the Toxic Substance Control Act of 1976, as amended, and the Rules and Regulations and Standards issued thereunder, and all other laws, rules, and regulations of federal, state, and local governments and agencies are and will be complied with regarding performance due under this Order.
- 17. Rights and Remedies Cumulative. Any rights and remedies granted in any part of this Order shall not be exclusive of, but shall be in addition to any other rights or remedies granted or provided by aw.

#### 18. Interpretation.

- a. This agreement is executed and delivered in the state of Wisconsin. Should any dispute arise between Seller and Phillips-Medisize, it is agreed that Wisconsin law shall apply to the interpretation and meaning of this agreement and, further, Wisconsin courts shall be the only forum for such disputes. Each party hereby consents to and submits to the exercise of jurisdiction over its person by the appropriate Wisconsin court having jurisdiction.
- b. If, at any time hereafter, a court of competent jurisdiction should hold that any terms, condition, or provisions contained herein shall be invalid, unenforceable, or unlawful, then it is agreed by the parties hereto that such ruling shall not affect any other term, condition, or provision contained herein and all of the other terms, conditions and/or provisions not so ruled, shall remain in full force and effect.
- 19. Entire Agreement. This Order, and any documents referred to on the face hereof, constitute The entire agreement between the parties. The terms of any document referred to on the face of this Order shall control in the event of any conflict with the printed provisions of this Order.
- 20. No Waiver. No failure by any party to this agreement to exercise any right hereunder shall operate as a waiver of any right hereunder, and a waiver of any right on one occasion shall not constitute bar to or a waiver of any such right on any future occasion, whether of the same or similar type.
- 21. Captions. Captions preceding particular paragraphs are for convenience only and are not to be construed a part of this Order or as a limitation of the scope of a particular paragraph to which they refer.

## **COMMERCIAL REQUIREMENTS**

## **B.01 Purchase Orders and Releasing System**

## **Purchase Orders**

Commitments for the purchase of material or services can only be made through issuance of a Phillips-Medisize, LLC purchase order. Phillips-Medisize, LLC Purchasing personnel are the only personnel authorized to make purchase commitments. Verbal purchase commitments from Phillips-Medisize, LLC personnel other than Purchasing will not be considered binding. Phillips-Medisize, LLC purchase orders or purchase order changes are not valid unless signed by the Phillips-Medisize, LLC Purchasing Manager/Agent or designee. All changes in delivery, quantity, price, print revision level, terms, etc. to issued purchase orders will be communicated to the supplier via Fax, phone, EDI, US mail or email.

# **Acknowledgement of Purchase Orders**

All purchase orders sent to the supplier must be promptly acknowledged and returned to Phillips-Medisize, LLC Purchasing within 24-hours. The acknowledgment must clearly indicate any exceptions taken to the purchase orders by the supplier. If the supplier does not return the acknowledgment, the entire contents of purchase orders are considered valid and binding on the supplier. Acknowledged delivery dates will be the basis for assessment of the supplier's delivery performance.

The supplier must submit a 30-day written notice to the Phillips-Medisize, LLC Purchasing department when a price increase is proposed. A supplier must also include supporting evidence of cost drivers. After acceptance of price increase proposal, Phillips-Medisize, LLC requires a 30-day implementation period.

## Releasing and Scheduling of Production Purchase Orders

Phillips-Medisize, LLC operates two distinct types of purchase orders, blanket purchase orders and spot buy (discrete) purchase orders.

Blanket orders define a time-bounded contract that allows repetitive release of shipping requirements in accordance with Phillips-Medisize, LLC production schedule. The actual firm quantity commitments will be communicated by the Phillips-Medisize, LLC Purchasing Department.

Spot Buys are purchase orders for a specific quantity to be delivered on the date specified on the purchase order.

## **Certification Requirements**

When required on the purchase order, a certificate must be sent prior to or with each shipment. Unless otherwise required, the certification will include:

- A statement that the material purchased meets the specifications listed on the print and/or purchase order
- Material type and number
- Purchase Order number
- Date Shipped
- Any additional requirements listed on the purchase order or specification
- Revision level
- Lot Number
- Quantity or units per-lot

## **B.02 On-Time Delivery**

Phillips-Medisize, LLC Requires 100% on Time Delivery from All Suppliers. The purchase order dates are Phillips-Medisize, LLC in house dates and not the supplier's ship dates. The supplier is responsible to ship the material to arrive at Phillips-Medisize, LLC in the required time frame. Failure to meet the in-house date will jeopardize Phillips-Medisize, LLC production and result in the supplier being responsible for any premium transportation required to insure uninterrupted supply. In addition, the supplier may be required to provide corrective actions for any shipments that are not 100% on time. The supplier must immediately notify Phillips-Medisize, LLC if a delivery date cannot be met.

## **B.03 General Shipping Requirements**

All unauthorized shipments may be returned to the supplier, at the supplier's expense, by the discretion of Phillips-Medisize, LLC Purchasing Department.

- Parts not shipped in time to meet the purchase order due date may require premium transportation and will be the responsibility of the supplier.
- For all shipments that are past due, the supplier must fax or email forwarding information to the Phillips-Medisize, LLC purchasing department.
- All communication concerning inbound shipments should be made with Phillips-Medisize, LLC purchasing.
- The invoice and packing slip must contain purchase order number, part number, quantity, date, lot number, Phillips-Medisize, LLC's internal number and Revision where applicable.
- One invoice per purchase order number per shipment.
- The supplier shall pay any additional costs incurred by shipping with a carrier other than specified by Phillips-Medisize, LLC.

# **General Shipping Routing Instructions**

Recommended weight break for Parcel shipments verses LTL shipment:

- Less than 350 lbs. total shipment weight Parcel (Ship via Phillips-Medisize, LLC Preferred Parcel Carrier Account):
  - o A single parcel fully encased in cardboard that weighs between 12 & 50 lbs.
  - o Length + Girth does not exceed 165 inches
  - Non-hazardous
  - o Does Not Require a pallet
  - o No drums
  - o Total shipment weight not to exceed 350 lbs.
  - o Supplier will ship Ground unless otherwise stated
- Greater than 350 lbs. total shipment weight LTL (ship via Phillips-Medisize, LLC Preferred Freight Carrier – contact your Phillips-Medisize, LLC Purchasing Agent for specified carrier)
- For Truckload shipments contact your Phillips-Medisize, LLC Purchasing Agent for specified carrier
- No Insurance/No Declared Value:
  - The Insurance Liability of any shipment is the responsibility of the Shipper (supplier). Any Declared Value charges should NOT be billed to Phillips-Medisize, LLC
  - o If you decide to select Declared Value you must check the box that states, "Shipper Paid"
- Do Not Prepay and Add Freight to Invoice
- Supplier will ship collect per Phillips-Medisize, LLC's preferred carrier of choice unless otherwise stated contact a Phillips-Medisize, LLC Purchasing Agent for specified carrier.

The supplier must provide the Phillips-Medisize purchase order number to the carrier and the Phillips-Medisize, LLC purchase order number must be referenced on the carrier Invoice.

• Shipments not referencing the Phillips-Medisize, LLC purchase order number on the Carrier invoice will have the shipping cost charged back to the shipper (supplier).

 Phillips-Medisize, LLC will not pay surcharges and/or shipping and handling charges on the supplier invoices but will pay for merchandise only, unless other terms have been negotiated.

## **B.04 Bar Code Label Standard Requirements**

- FORMAT: Phillips-Medisize, LLC has an approved label as detailed below
- **OVERALL SIZE**: The label size shall be 4 inches x 6.5 inches (102 mm x 165 mm)
- DATA FIELDS: Each field shall be separated by a thin line and shall contain its title and field identifier. 1.2
- TITLE: Titles are mandatory and shall be printed in at least 0.07-inch minimum high characters.

#### The data field titles are:

FIELD NAME	<b>BAR CODED</b>	FIELD TITL
Part Number	Yes	Part No.
Quantity	Yes	Quantity
Part Name	No	Part Name
Supplier	Yes	Supplier
Purchase Order Number	Yes	P.O. Number
Revision Level	No	Part Revision
Manufacturing Date	No	Mfg. Date
Lot Number	Yes	Lot

#### **Data Field Identifiers**

The following is a list of identifiers that should precede the information in each bar-coded field.

P - Phillips-Medisize, LLC part number

Q - Quantity

V - Supplier Number

K - Phillips-Medisize, LLCs purchase order number

S - Serial (Lot) number

#### **Mandatory Data Fields**

All fields are mandatory.

# Field Length and Size

The following is a list of characters for field length and height.

Part Number	-	25 Characters	0.5 inches high
Quantity	-	9 Characters	0.5 inches high
Part Name	-	35 Characters	0.25 inches high
Supplier	-	10 Characters	0.25 inches high
P.O. Number	-	15 Characters	0.25 inches high
Revision Level		15 Character	0.25 inches high
Lot Number	-	25 Characters	0.25 inches high
Manufacturing Date	-	8 Characters	0.4 inches high

## **Bar Code Symbolism**

Shall be CODE 39.

#### **Code Density**

Shall be at least 2X, preferably 3X.

## **Label Placement**

Label should be placed on containers as follows.

Resin Bags - On the center of the bottom of the bag.

Gaylords - On the upper right-hand corner of the largest face.

Barrels - On the center of the side.

Boxes - On the lower right-hand corner of the smallest face.

Components - On the upper corner of the box and all bags Subcontracted Parts - On the upper corner of the box and all bags

## **Packing list**

- · A packing list is required on all shipments.
- One Purchase Order number per packing slip.
- Packing lists must contain the purchase order number, part number, quantity, date, lot number, Revision and Phillips-Medisize, LLC part number.

### **B.05** Request for Quotation

Phillips-Medisize, LLC will generate a Request for Quote (RFQ) to suppliers for new products or services. Phillips-Medisize, LLC reserves the right to issue an RFQ to potential (pending) suppliers.

#### **RFQ Procedure**

It is Phillips-Medisize, LLC's stated policy to align itself with suppliers that are capable of demonstrating the controls required to manage their business. Phillips-Medisize, LLC at minimum enters into supplier relationships with companies that are ISO9001 certified for all automotive and Medical applications or companies that can demonstrate that a well-organized effort toward IATF 16949 and/or ISO 13485 compliance is underway. Phillips-Medisize, LLC firmly believes that the disciplines required under ISO 9001, IATF 16949, and ISO 13485 is fundamental to success in our industry.

If a supplier does not meet the above criteria, Phillips-Medisize, LLC Purchasing and Quality departments may grant an approval/waiver (note that customer approval may also be required). Phillips-Medisize, LLC may consider the type of product supplied, supplier's Quality system, Manufacturing and Delivery systems, supplier capability and risk prior to granting any approval/waiver. Authorized Phillips-Medisize, LLC Purchasing and Quality representatives will have the authority to grant approval/waiver, per the above, and will maintain records as to the details of why the approval/waiver was granted.

Accordingly, Phillips-Medisize, LLC Purchasing is required to qualify suppliers through a prescribed method, which verifies the existence and use of controls consistent with the ISO9001, IATF 16949 and ISO 13485 standards. Prior to issuance of an RFQ, Purchasing will reference the Phillips-Medisize, LLC "Preferred Supplier List" to locate current suppliers that may be capable of supplying the product or service. If a match for the RFQ is not found, Purchasing will initiate a search for a new supplier. The steps required to qualify a new supplier are shown in the section titled "Supplier Approval and Evaluation."

Upon selection of a current approved supplier, or successful qualification of a new potential supplier, Phillips-Medisize, LLC Estimating or Purchasing department will forward an RFQ to the supplier. RFQ's normally contain the following items:

- Phillips-Medisize, LLC RFQ Form
- Uncontrolled Drawing of the item to be quoted
- Related specification sheet

When the supplier quotes the item(s), it is preferable that the Phillips-Medisize, LLC RFQ form be used to detail the quotation as the data is organized for ease of use within Phillips-Medisize, LLC. If the Phillips-Medisize, LLC RFQ is not used, then the following minimum information is required for the quotation to be considered:

- Name of the Phillips-Medisize, LLC Buyer that sent the RFQ
- Phillips-Medisize, LLC part number
- Piece part price, per the break quantities in the RFQ
- Complete tooling costs required
- Detailed description of tooling
- Capacity of tooling, per eight (8) hour shift
- Lead time for tooling completion, prototype, and production

- Lead time for tooling de-bug (estimated)
- Lead time for initial samples
- Lead time for production after sample approval
- Any additional costs, such as set up charges, sample run charges, minimum material commitments, validation activities, etc.

Any questions, technical or otherwise, from the supplier regarding the request for quotation should be addressed to Phillips-Medisize, LLC Purchasing. Depending on the complexity of the part specification, a Non-Disclosure Agreement (NDA) may be required.

## **B.06 Business Resumption Plan**

A supplier may be requested to maintain a Business Resumption Plan that covers the following:

- Safety Stock per the appropriate schedule
- Utility interruptions
- Transformer back-ups
- · Labor Shortages
- Equipment failures
- · Catastrophic emergencies
- Recovery plans
- Data/computer system back-ups

## **B.07 Safety**

- Material Safety Data Sheets and Environmental Data Sheets must be submitted for approval prior to any initial shipment and when up-dates or changes are made.
- Suppliers are required to adhere to all local, state and federal regulations where applicable, such as OSHA and ANSI codes.
- All material should satisfy current governmental and safety constraints on toxic, restricted and hazardous materials, as well as environmental, electrical and electromagnetic considerations applicable to the country of manufacturing and sale.
- Equipment/machines must meet or exceed machine wiring standard NFPA79.

## **B.08** Environmental/Regulatory

It is our policy to develop and maintain supplier relationships with firms that embrace similar environmental goals and guidelines. We recommend that our supplier strive for ISO14001 compliance with the ultimate goal of ISO14001 certification.

In keeping with this policy, our objective as a Corporation is to reduce waste through source reduction and recycling and to achieve minimal adverse impact on the air, land and water through excellence in environmental control.

## RoHS2:

It is Phillips-Medisize, LLC's objective to meet the RoHS2 requirements. However, in order to achieve this, our suppliers must provide us with product free of the restricted substances, per the latest, European Union RoHS2 directive.

We will not purchase any material/product that contains any of the banned RoHS2 substances without our customer's approval.

#### ISPM 15/TBA/TCA:

Phillips-Medisize, LLC suppliers need to be aware of and compliant to the solid wood packaging (pallets, etc.) requirements of the International Standards for Phytosanitary Measure 15 (ISPM 15). This standard states that any wood packaging, which crosses national borders (including from Canada and Mexico), must be bug free through accepted methods of either Heat Treatment (HT) or Methyl Bromide Fumigation

(MB). This standard may be subject to special requirements, per specific customer requests, which will be communicated on a case-by case basis. The entire standard can be found at <a href="www.ippc.int">www.ippc.int</a>.

The U.S. Government upon entry into the U.S. will inspect wooden boxes, or other solid wood packaging material. If the required International Mark is not found on the wood, the shipment will be returned to the supplier at their cost.

Similarly, <u>Tribromoanisole (TBA) or Trichlorophenol (TCA)</u> is a moldy-type residue created by a biomethylation reaction to Tribromophenol (TBP) or Trichlorophenol (TCP). TBP and TCP are used as a fire-retardant and/or wood preservative in construction materials, pallets, paper products (registered for use in Latin America, known to be used in Eastern Europe and Northern Asia according to AFGC). It is our aim to ensure our suppliers do not use pallets or paper products that may have been treated with TBP or TCP.

#### **ELV/IMDS:**

Phillips-Medisize, LLC is ELV/IMDS compliant per customer specific requirements. In order for us to maintain this compliance, we require the supplier's assistance, when necessary, for the identification and reporting of the chemical compounds / basic substances present in the parts we provide to our customers.

### **REACH:**

It is Phillips-Medisize, LLC's objective to meet the most current REACH (Registration, Evaluation, Authorization and Restriction of Chemical Substances) requirements.

Per this EU Regulation, our suppliers, when applicable, are to register the chemical substances present in their product. Websites that will help in understanding the requirements and if applicable: <a href="http://reach.aiag.org/">http://reach.aiag.org/</a> and <a href="http://www.euractiv.com">www.euractiv.com</a>.

Also, our suppliers must provide us with product free of the identified SVHCs (Substances of Very High Concern). While some chemicals have been identified, the list is periodically updated. Consequently, our suppliers are expected to monitor the REACH website for the latest update.

When requested, suppliers will provide Phillips-Medisize, LLC with certificates of compliance verifying compliance of their products to REACH directives and registration of all applicable SVHC's

## **Conflict Minerals**

The Dodd-Frank Act of 2010 mandated that the United States Securities and Exchange Commission (SEC) issue a ruling requiring companies to disclose whether they source certain minerals from Central Africa (the Democratic Republic of the Congo and adjoining countries). On August 22, 2012, the SEC issued a final Conflict Mineral rule under section 1502 of the (Dodd-Frank) Wall Street Reform and Consumer Protection Act. The Conflict Mineral Rule requires publicly traded companies to report, annually, the presence of conflict minerals (tin, tungsten, tantalum and gold or "3TG"), originating in the Democratic Republic of the Congo or adjoining countries, in their final product. As part of the due diligence required by those companies to achieve Conflict Mineral compliance, they are required to ensure that their vendors do not source any of the specified conflict minerals from the "conflict region".

## **Conflict Minerals - Definition**

(A)columbite-tantalite (coltan), cassiterite, gold, wolframite or their derivatives (tin, tungsten or tantalum) or (B) any other mineral or its derivatives determined by the Secretary of State to be financing conflict in the Democratic Republic of the Congo or adjoining countries per SEC 1502 regulations. To qualify as a conflict mineral, the mineral in question must be necessary to the functionality or production of the product and must be retained in the end product.

Although not publicly held, Phillips-Medisize, LLC will commit to:

- Support the aims and objectives of the U.S. legislation regarding Conflict Minerals.
- Assist our customers in implementing their Conflict Minerals programs.
- Not knowingly procure specified minerals that originate from facilities in the "conflict region" that are not "conflict free".
- Ensure compliance with these requirements and ask our suppliers to undertake due diligence with their supply chains to assure that specified metals are being sourced only from:
  - Mines and smelters outside the "conflict region"
     OR
  - Mines and smelters, which have been certified by an independent third party as "conflict free" if sourced within the "conflict region"

When requested, suppliers will provide Phillips-Medisize, LLC with signed off documentation verifying their products as "conflict mineral free".

If we discover the use of these minerals, mined or produced in mines/facilities that are considered "non-conflict free", in any material, parts or components we procure, we will take the appropriate actions to work with our customer base to transition products to be "conflict free".

# Phthalates

Phthalates are esters of phthalic acid. They are mainly used as plasticizers (substances added to plastics to increase their flexibility, transparency, durability, and longevity) and are used primarily to soften polyvinyl chloride (PVC). Phthalates are being phased out of many products in the United States, Canada, and European Union over health concerns. Phillips-Medisize, LLC has an aim to ensure phthalates are not present in our plastic materials.

### **Proposition 65**

The Safe Drinking Water and Toxic Enforcement Act of 1986, was enacted as a ballot initiative in November 1986. The Proposition was intended by its authors to protect California citizens and the State's drinking water sources from chemicals known to cause cancer, birth defects or other reproductive harm, and to inform citizens about exposures to such chemicals. As such, Phillips-Medisize, LLC aims to ensure chemicals listed on the most recent Proposition 65 list are not used in our finished product and require our supplier to ensure the components and raw materials sold to us are free of these chemicals.

## Latex

Latex is a natural rubber that is made from the sap of the Brazilian rubber tree. Hundreds of products may contain latex, most frequently medical devices. Since 1990, latex allergies have become a serious health care problem, therefore Phillips-Medisize, LLC aims to insure our products have not been in contact with latex.

#### Gluten

Gluten sensitivity is a problem that occurs when gluten, a protein derived from wheat, damages the lining of the intestines. As an allergy concern, it is important to ensure medical products have not been in contact with gluten.

# **B.09 Approved Material for Ongoing Production**

All materials used in part manufacture shall satisfy current governmental and safety constraints on restricted, toxic and hazardous materials; as well as environmental and electromagnetic considerations applicable to the country of manufacture and sale.

Systems must be established to allow this to happen. The supplier may be reviewed to ensure that the systems are present, fully understood and functional.

## **PRODUCT CONTROLS**

## **C.01 Change Control**

Suppliers must have written authorization from Phillips-Medisize, LLC Purchasing / Engineering Department before incorporating any changes into production. A written explanation adequately explaining the change should be used to communicate requested changes to the product, process or service. The supplier should contact the applicable Phillips-Medisize, LLC Purchasing and Quality departments for the appropriate process/system to communicate the change request.

A **change** is defined as any modification, alteration or enhancement from agreed upon products, processes, equipment, methods or services which may directly or indirectly affect the performance, fit, function, form or integrity of the product.

The supplier's system shall provide for records documenting effective dates of engineering changes, timely removal of obsolete material and identification of changed material delivered to Phillips-Medisize, LLC. Change control records shall be available for review by Phillips-Medisize, LLC representatives.

Shipments incorporating changes must be identified and shall not be made without authorization by Phillips-Medisize, LLC's Purchasing and Quality departments.

#### **C.02 Lot Control**

If requested by purchasing, the supplier is required to maintain a "lot control" system. Products and material should be traceable to laboratory reports, control documentation, materials and processing records. Phillips-Medisize, LLC Purchasing / Quality department must approve any deviations from this standard.

## C.03 Product Identification, Protection and Preservation

The supplier's system shall provide controls that assure that products are protected against damage, contamination and corrosion during processing, storage and shipping. Where applicable, the system shall provide storage controls for products with limited shelf life.

Packaging standards should be developed to ensure that product is transported in acceptable containers.

#### **C.04 Tool Purchases**

All tool purchases (purchasing of jigs, fixtures, gages, dies, automation and molds) must have a complete 3D and basic 2D tool design with a complete Bill-of-Materials (BOM), delivered with the tool. Exceptions to the requirements above are detail for hot runners or cold decks. For hot runners and cold decks the basic external shapes need to be included.

All tool modifications or Engineering changes require that an updated 3D and basic 2D tool design with a complete BOM be delivered with the tool.

#### SUPPLIER APPROVAL and EVALUATION

# **D.01 Supplier Selection Criteria**

Phillips-Medisize, LLC selects and approves suppliers based on a risk assessment prior to purchasing new products. Once a supplier is tentatively selected, the Phillips-Medisize, LLC team ranks the proposed new supplier based on the Quality Risk and the Supply Risk. Once the supplier is ranked an overall risk level is assigned for that supplier:

- A. Critical
- B. Major
- C. Minor
- D. Commodity

This overall risk level determines the controls needed for approving the supplier. Some of the considerations include:

- 1. Satisfactory completion of a supplier self-assessment or on-site audit
- 2. ISO or QS certifications
- 3. A completed Supplier Quality Agreement

**Summary:** Phillips-Medisize, LLC being a "World Class Supplier" requires participation by suppliers who share the same goal. Phillips-Medisize, LLC depends on its suppliers for key operations. Suppliers who continually improve will continue to receive business and support.

# **D.02 Supplier Monitoring**

If requested, current Suppliers will be required to complete a self-assessment. This will be accomplished every 3 years. On-site audits will be required for suppliers with increased levels of risk. These audits will be completed every 2 years. For suppliers in good standing (i.e. no recent corrective actions and high supplier scorecards) a self-assessment may be accomplished in lieu of an on-site audit. Phillips-Medisize, LLC's Purchasing / Quality or Purchasing personnel may conduct on-site audits as required, when applicable. Supplier class and status is determined on the significance of the product and the evaluation of the above elements by Phillips-Medisize, LLC Purchasing and Quality.

## CONTINUOUS IMPROVEMENT/SUPPLIER DEVELOPMENT

#### **E.01 Cost Reduction**

The supplier shall work with Phillips-Medisize, LLC to actively pursue cost reduction on an ongoing basis. The supplier will offer technical support to aid Phillips-Medisize, LLC in the pursuit of cost and scrap reduction. All cost reduction activities put forth by the supplier shall be reported to Phillips-Medisize, LLC Purchasing department for documentation.

#### E.02 Supplier Development

As mentioned above, Phillips-Medisize, LLC has employed a risk-based system to categorize and develop its suppliers.

The following is the supplier development strategy per each classification:

## A Suppliers

- Current supply agreement on file
- Quarterly supplier report cards
- Annual supplier review meeting
- Price and performance vs. benchmarked expectations

#### **B** Suppliers

- Terms and Conditions conveyed
- Annual supplier report cards
- Price and Performance vs. benchmarked expectations

## C and D Suppliers

- Terms and Conditions conveyed
- Price and Performance vs. benchmarked by Commodity

It is Phillips-Medisize, LLC's stated policy to align itself with suppliers that are capable of demonstrating the controls required to manage their business. To this end, Phillips-Medisize, LLC will work to develop its supply base with the goal of aligning its suppliers to the Automotive market segment with IATF 16949 and its Medical suppliers with ISO 13485. It is Phillips-Medisize, LLC's intent that its suppliers' Quality Management Systems be compliant with the applicable standards, if not actually certified.

#### **NONCONFORMANCE**

# F.01 Detected at Supplier Location

Phillips-Medisize, LLC requires 100% acceptable product from all suppliers. Should nonconforming product be discovered, the supplier must immediately determine the extent of the condition and take prompt corrective actions to prevent shipment of all nonconforming material that have been released. The supplier must notify Phillips-Medisize, LLC's Purchasing / Quality Department, warning them of the condition. The supplier must describe the method of segregation and the containment actions being enforced to control the condition. If any nonconforming material containment action fails the supplier will be responsible for sorting or returning the product at Phillips-Medisize, LLC. If the problem cannot be sorted out, shipments must be held pending specific instructions from the Phillips-Medisize, LLC Purchasing / Quality department. Supplier communications notifying Phillips-Medisize, LLC of a nonconforming condition and positive corrective action should be directed to Phillips-Medisize, LLC Purchasing / Quality Department.

# F.02 Detected at Phillips-Medisize, LLC

In the event that non-conforming material is detected at Phillips-Medisize, LLC, the Quality Department will notify the supplier and arrange for disposition. The Purchasing / Quality Department may require a supplier to be present during the evaluation of any nonconforming material at Phillips-Medisize, LLC.

Costs incurred in returning shipments or sorting nonconforming product is the responsibility of the supplier. These costs can include but are not limited to material, shipping, handling, direct and indirect labor or contracted services. When expediency requires such measures, nonconforming product will need to be sorted at the Phillips-Medisize, LLC facility. The supplier will be notified, in a timely manner, of the need to sort product, at the supplier's expense, at a minimum rate of \$35.00 per hour. The supplier may respond by sending in personnel to sort product on location or expedite a certified shipment.

Per non-conforming product disposition, the supplier may receive a Supplier Return Request or Corrective Action Request, which would require an action plan.

#### F.03 Detected Through Customer Claim

Upon determination that nonconforming product, directly attributable to a supplier, has resulted in a Phillips-Medisize, LLC customer claim, the supplier will be required to reimburse Phillips-Medisize, LLC for the associated costs incurred. Reimbursement may include but is not limited to the cost of the material, handling, shipping, and labor.

# **REVISION HISTORY**

	REV	Section		Page
01/05/06	Α		Released	
02/07/07	В	B01	RFQ: Up-date ISO9001:2000 and TS16949 requirement	4
			wording.	
			Acknowledgments of POs: added 30-day increase notice.	4
			Bar Code: Added revision level to the label requirements.	
			Changes serial # to Lot#	4
			General Shipping Requirements: added the word revision,	
			General: Up-date ISO9001:2000 and TS16949 requirement	4
			wording.	
		D01	Added third paragraph	12
			Added the word minimum to sorting rates.	
		A04	Added the word minimum to sorting rates.	2
		F08	•	22
		G02		23
06/4/07	С	All	Changed Corp to Corporation	
		pages	Corrected clerical errors	
			Added Approval to page title	25
		H01		<u> </u>
08/13/07	D	Pg. 5	Bar code Field Size up-dated	5
10/15/08	Е	B.02	Added Note in RFQ Procedure	7
10/15/08	Е	B.05	RoHS - Deleted exemption for DecaBDE's	9
10/15/08	Е	B.05	Added REACH statement	10
10/15/08	Е	C.01	Added Language to make provision for a waiver per note in	11
			B.02 (RFQ Procedure)	
10/15/08	Е	D.01	Added reference to B.02 (RFQ Procedure)	14
10/15/08	E	D.03	Deleted reference to SREA form. Added	14
10/15/08	E	E.03	Added Supplier Development to header. Added explanation	20
			of ABC Supplier Classification Criteria and development	
			plan.	
10/15/08	Е	All	Corrected various clerical errors	
10/15/08	Е	F.08	Added (Nonconforming Contingency Plan) after Production	25
			Shipments.	
10/15/08	Е	H.05	Added Special Processes language.	29
6/03/09	F	A.06	Added Equal Opportunity and Affirmative Action	2
6/03/09	F	A.07	Changed Terms & Conditions from A.06 to A.07 and	4
0,00,00		7	changed Payment Terms from N30 to N60 in Section 8	
2/11/10	G	G.02	Removed the \$250 minimum charge for Non-conformances.	27
2/11/10	Ğ	All	Removed the year after each ISO9001 and TS16949	All
0				pages
2/11/10	G	A.01	Added statement "to strive to provide its customers with	1
_, ,		7 0	quality and service second to none through continuous	
			improvement".	
2/11/10	G	A.06	Changed "upgrades" to "advances" in first paragraph and	2
2, 1 1, 10		700	removed "except where an accommodation is unavailable	-
			and/or it is a bona fide occupational qualification".	
2/11/10	G	B.01	Added General Shipping Routing Instructions	6
2/11/10	G	B.05	Added statement to ISPM 15 "This standard may be subject	10
_, ,	~	2.00	to special requirements, per specific customer requests	'
	1		which will be communicated on a case-by case basis."	
10/1/2012	Н	B.01	Added statement to Acknowledgement of Purchase Orders	5
10/1/2012	' '	5.01	"A supplier must also include supporting evidence of cost	
		1	1 7 Cappilor made also molado supporting evidende di cost	1
			drivers. After acceptance of price increase proposal,	

40/4/0040	1	I A II	Louisia Louisia Buring and Company and	LAU
10/1/2012	H	All	Separated Quality Requirements from Commercial Requirements and deleted Quality Requirements.	All pages
10/1/2012	Н	All	Deleted Quality Plan, Training, Preventative Maintenance,	All
10/1/2012	' '	' '''	and Management Review under the Continuous	pages
			Improvement section.	1 3 3 3
10/1/2012	Н	All	Deleted the Sample Submission Requirements (AIAG	All
			PPAP).	pages
10/1/2012	Н	All	Removed Corrective Action Plan Certified Stock under the	All
10/1/2012	Н	All	Nonconformance section.  Revamped and re-aligned Supplier Approval and Evaluation	Pages
10/1/2012	-	All	section.	All pages
10/1/2012	Н	B.06	Added Business Resumption Plan under the Commercial	9
			Requirements section.	
10/1/2012	Н	B.05	Added "Depending on complexity of the part specification, a	9
			Non-Disclosure Agreement (NDA) may be required".	
10/1/2012	Н	B.08	Under RoHS: Deleted "noted in Directive 2002/05/EC of the	10
			European Union" Added "per the latest European RoHS directive". Deleted list of banned substances.	
1			Deleted "above noted" and added "banned RoHS"	
			Deleted above floted and added ballifed Koris	
			Under REACH: Added "most current" REACH	
			requirements. Deleted "noted in the EU Regulation	
			EC/1907/2006". Deleted "While the following 16 chemicals	
			have been identified". Deleted SVHC table. Amended last	
			paragraph: "When requested, suppliers will provide Phillips-	
			Medisize Corporation with certificates of compliance	
			verifying compliance of their products to REACH directives	
			and registration of all applicable SVHC's.	
10/1/2012	Н	B.02	Changed "on date required" to "expected time frame".	6
			Changed "is expected" to "may be required"	
10/1/2012	Н	F.02	Changed to "Per non-conforming product disposition, the	14
6/26/2013	1	B.08	supplier may." Changed "will" to "would"  Changed section title from "Environmental" to	0.40.44
0/20/2013	1	D.00	"Environmental/Regulatory"	9,10,11
6/26/2013	I	B.08	Added policy statement regarding Conflict Minerals	10
6/26/2013	I	F.01	Added statement "Phillips-Medisize Corporation requires	15
			100% acceptable product from all suppliers".	
3/21/2014	J	B.05	Changed "Supplier Evaluation" to "Supplier Approval and	8
			Evaluation"	
3/21/2014	J	B.08	Added the following statements: TBA/TCA; Phthalates;	10,11
3/21/2014	1	D.01	Proposition 65; Latex and Gluten  Changed title to "Supplier Approval and Evaluation"	13
3/21/2014	J	D.01	Incorporated new system for supplier selection. Deleted old	13
3/2 1/2017	Ĭ	2.01	supplier selection criteria. Deleted old supplier evaluation	.5
			criteria.	
3/21/2014	J	D.02	Changed "Auditing" to "Monitoring". Added "this will be	14
			accomplished every 3 years". Added language regarding	
			on-site audits.	
3/21/2014	J	E.02	Deleted "three tier" added "four-tiered, risk based". Deleted	15
			A, B and C Criteria. Changed B supplier to annual supplier	
			report cards. Deleted B supplier "Supplier review meeting	
			every 18 months". Deleted "Annual supplier report cards" from C and D suppliers. Added statement regarding	
			developing suppliers to ISO TS16949 and 13485 standards.	
2/12/2015	K	C.04	Added section defining requirements for tool purchases	14
		0.01	1	

10/2/2017	L	All	Updated company name to Phillips-Medisize, LLC Corrected typographical errors	All
10/2/2017	L	D.01 E.02	Updated criteria for supplier classification to be based on Quality Risk and Supply Risk	15
			Changed "self-survey" and "desk audit" to "self-assessment" and changed "in-person audit" to "on-site audit" for consistency.	
10/2/2017	L	F.02	Changed Corrective Action Report to Corrective Action Request	16
10/2/2017	L	B.05, E.02	ISO/TS 16949 updated to IATF 16949	10, 16