



Klarity Medical Products, LLC  
600 Industrial Parkway  
Heath Ohio 43056 USA  
tel: 740.788.8107  
fax: 740.788.8109  
info@klaritymedical.com  
www.klaritymedical.com

## SUPPLIER PURCHASING POLICY

1	Purpose	
2	Scope.....	1
3	Limitations.....	1
4	Definitions.....	2
5	Details.....	3
5.1	Purchasing Policy.....	3
5.2	Code of Conduct.....	3
5.3	Information, Purchase orders, Production forecast, Non-conforming material.....	4
5.4	Delivery and packaging requirements.....	6
5.5	Invoicing.....	8
5.6	Complaints.....	9
5.7	Supplier Follow-up.....	9
5.8	Design control.....	11

# **1 PURPOSE**

The purpose of the Supplier Purchasing Policy is to inform suppliers about Klarity's general supplier requirements and processes.

# **2 SCOPE**

This document applies to all suppliers in category 1 and 2. It informs suppliers about Klarity's Purchasing policy, Code of Conduct, Delivery and Packaging Requirements, Invoicing, Complaints, Supplier Follow Up and Design Control.

# **3 DETAILS**

## ***3.1 Purchasing Policy***

It is Klarity's policy to work with approved suppliers that are financially stable, have an adequate technical ability, a quality system that complies with the standards required for the products they will be supplying, and that suppliers continue to meet Klarity's requirements.

## ***3.2 Code of Conduct***

The Klarity Code of Conduct sets out basic principles in order to promote honest and fair behavior as well as integrity, trust, and reliance in the business of Klarity. Living up to these principles will enhance Klarity's ability to contribute to sustainable development in the countries where Klarity operates. Klarity expects all its suppliers to follow these principles as well.

The Code focuses on the following general, social, environmental and economic principles:

### General

Everyone at Klarity must abide by laws and regulations applicable within each specific area, country, as well as line of business etc, in which Klarity is active. They must also comply with all relevant disclosure requirements applicable to Klarity.

### Social

Klarity ensures fair employment practices by ensuring equal opportunities in employment. Klarity will also respect employee rights; by striving for a healthy and safe environment, ensuring freedom of association and collective bargaining, protecting employees against inhumane or degrading physical and psychological treatment, securing living wages, ensuring the right to rest, leisure and paid holidays, combating exploitative child labor and avoiding forced or compulsory labor.

Everyone at Klarity must respect personal privacy, and strive to obtain the highest possible degree of product safety.

### Environmental

Klarity strives to act in an environmentally responsible manner by minimizing the environmental impact of Klarity's business, and products.

### Economic

Klarity will not engage in unlawful improper payments or transactions, such as bribery, fraud, money laundering etc. Klarity also avoids conflicts of interest. Klarity utilizes resources carefully and for the purpose of conducting Klarity business. Klarity respects competitive regulations, and insider trading rules, as well as confidentiality, both internally and in our relationship with customers and Klarity Partners.



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### ***3.3 Information, Purchase orders, Production forecast, Non-conforming material***

#### **CONTACT PERSON**

For each supplier, Klarity has a Strategic purchaser responsible for contract, supplier assessment, follow up and capacity issues.

The contact person at Klarity for each purchase order is stated on the purchase order; all questions on the specific order shall be with the contact person.

For contact:

Attn: Purchasing

Klarity Medical Products, LLC

600 Industrial Parkway

Heath, OH 43056 USA

[purchasing@klaritymedical.com](mailto:purchasing@klaritymedical.com)

ph. 740-788-8107 x105

#### **PRODUCTION FORECAST**

Suppliers will maintain a delivery capacity which permits them to deliver the products in accordance with forecasts and purchase orders.

Klarity, at its discretion may provide production forecasts for the products. Such forecasts shall not be binding and shall not include any obligation to purchase the forecasted numbers of products.

#### **PRODUCTION STOP / OBSOLESCENCE**

If a supplier or sub supplier is going to stop producing a product that Klarity buys, the supplier must inform Klarity a.s.a.p. in order to avoid delivery disruptions to Klarity.

#### **NON-CONFORMING MATERIAL**

The products shall be manufactured and delivered in compliance with the specification. Manufacturer shall not be entitled to make changes to the products or the specification without Klarity's written approval.

The use of non-conforming material, failure to meet product performance and specification or deviation from quality and regulatory requirements and directives is prohibited without explicit Klarity written authority.

A formal request (Non Conformance Report) for the use of non conforming material, failure to meet performance specification or deviation from the quality and regulatory requirements shall be submitted to Klarity in sufficient detail for a full assessment to be made.



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The non conformance report must include the following:

- Part number
- Issue/revision number
- Item name (part description)
- Product/project (if applicable)
- Originator
- Manufacturer
- Date
- Order number
- Description of deviation
- Suggestion to solve deviation (if possible)
- Batch number/Serial number (if applicable)
- Corrective action (if possible)

Klarity will evaluate the Non Conformance Report and send an answer to the supplier. The answer will include an action plan or a non-approval.

The supplier may use their own form, or request access to the Klarity non conformance form.

## **PURCHASE ORDER**

Klarity shall order the products by sending written purchase orders to supplier. Such orders shall include the Delivery Date for the products. Supplier shall confirm all such orders within four (4) days of receipt. Purchase orders not rejected within four (4) days of receipt, shall be deemed accepted.

Following information must be submitted to, or by Klarity:

	Purchase order (by Klarity)	Order acknowledgement (from supplier)
Reference to purchaser	X	X
Purchase order number	X	X
Part number	X	X
Issue/revision number	X	X
Supplier(address and reference)	X	X
Delivery address	X	X
Invoice address	X	
Price and currency	X	X
Terms of payment	X	X
Quantity (unit)	X	X
Delivery date	X	X
Instructions (e.g. order acknowledgement in 4 days)	X	

## **3.4 Delivery and packaging requirements**

### **GENERAL**

The Products shall be packed, marked and shipped by Manufacturer in accordance with Klarity's instructions and good commercial practice so as to ensure that the products are not damaged. Manufacturer shall deliver the Products to the recipient indicated by Klarity in the Purchase Order at the address set out therein. Unless otherwise agreed in writing delivery shall be made DDP (Incoterms 2020), Klarity Heath, Ohio.

Packaging should be minimized, suitable for recycling, composting or incineration, be free of heavy metal contamination. Wooden packaging must comply with ISPM15.

Product inspection/test result sheets where specified in the Delivery Check Report shall be attached to the item.

All items on the Purchase order shall be individually packed and labeled.



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## **HAZARDOUS GOODS**

When shipping hazardous goods the case, packing and marking shall be in accordance with International Air Transport Association ("IATA") regulations for each hazardous product. Appropriate documents should be filled in and attached according to IATA regulations.

The supplier must enclose MSDS (Material Safety Data Sheet) in the delivery with the hazardous product. There must be two copies of MSDS, one on the inside, and one on the outside of the package.

## **ELECTRONIC STATIC DISCHARGE ("ESD") REQUIREMENTS**

Supplier shall have an environment relevant to the requirements defined below for the parts that can be affected by ESD, which is specified in the product specification.

Electronic discharge sensitive device (ESDS) requires correct handling and precautions equivalent to, or exceeding the standards listed below.

Reference Standards:

IEC 61340-5-1: Protection of electronic devices from electrostatic phenomena – General requirements.

IEC 61340-5-2: read in conjunction with the above Standard

To fulfill the necessary ESD control, Supplier shall maintain relevant knowledge at the manufacturing personnel level and use necessary control equipment to avoid ESD damage.

The then current standards published by the Electrostatic Discharge Association (ESDA) or the American National Standards Institute (ANSI)

## **PRODUCT LABELING**

Each product on the purchase order shall be labeled in accordance with the specification.

The label shall state the following:

- Klarity (as company name)
- Item name
- Item number (part number)
- Lot/Serial number (when applicable)

## **SHELF LIFE**

Parts with an expiration date, must be clearly labeled on each single package with the following information:



- Production date
- Expiration date

**Requirements on Time left (to expiration date) on product shipped to Klarity will be found in the article specification.**



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## **DELIVERY DOCUMENTATION**

The delivery note shall state as a minimum:

- Delivery address
- Klarity part number and the revision number
- Lot/Serial number (when applicable)
- The quantity of supplied product
- Purchase order number and line

## ***3.5 Invoicing***

The invoice shall state as a minimum:

- Invoice number
- Name and address on sender and the recipient.
- US suppliers bank account number
- Foreign suppliers bank account number and SWIFT code
- Terms of Payment
- Klaritys correct company name: Klarity Medical Products LLC
- Quantity of supplied product
- Klarity Part and Revision number
- Purchase order number and line
- Price and currency

### ***3.6 Complaints***

If Klarity or Klarity customer discovers a problem, Klarity will request a formal Corrective Action.

Supplier shall respond in writing to complaints received within two weeks of receipt detailing the root cause of the reported complaint and the appropriate corrective/preventive action that shall be taken.

In the event of problems and/or complaints, Supplier will permit Klarity to assist in the investigation and identification of corrective action.

Klarity reserves the right to audit the Quality System and manufacturing facility at Supplier to verify corrective action if so requested in writing.

### ***3.7 Supplier Follow-up***

Klarity will perform a supplier Follow-up regularly in order to analyze and summarize the performance of deliveries and their ability to fulfill Klarity Requirements.

The results from the supplier Follow up will be used to identify the Supplier's performance, to optimize the use of good suppliers and to decide what actions to take against suppliers whose results are not acceptable.

### ***3.8 Design control***

#### **DESIGN CHANGES INITIATED BY SUPPLIER**

If Supplier wishes to undertake any design changes to Klarity supplied drawings then this shall be communicated by a change request to the person in charge at Klarity. No changes are to be made to the product without formal notification of agreement from the design authority at Klarity. The Change Request should be a formal written request and must be submitted to Klarity with all of the following information:

- KLARITY drawing number/Klarity Part Number
- Issue number
- Part description
- Reason for change
- Details of change
- Name of originator
- Date
- Unique reference number

## **DESIGN TRANSFER FOLLOWING DESIGN CHANGES**

Design transfers by Klarity are performed in order to transfer a released Change Order including bill of material, technical specifications and conditions for the release, to make the supplier understand the design, and what and how to deliver.

### **SUPPLIER RESPONSIBILITY**

Supplier shall:

- Inform effected sub-suppliers about final scope and time plan.
- Manage production in-house to minimize future scrap/rework.
- Manage production at sub-suppliers to minimize future scrap/rework.
- Start design of new/modified work instructions.
- Start design of new/modified inspection instructions.
- Invite effected sub-suppliers to pre-design transfer meeting.
- Inform and distribute preliminary specifications to effected sub-suppliers.
  
- Analyze predictability, finally (also at sub-supplier) feed back to Klarity.
- Finalize design of new or modified work instructions.
- Finalize design of new or modified inspection instructions.
- Perform training of operators.
- Report to Klarity for cost of rework, scrap, tools, investments and product price.
- Inform and distribute released specifications to effected sub-suppliers.
- Implement change or new product in production.
- Confirm change in production and report final rework/scrap/tool cost to Klarity.
- If applicable, validate new changed production process.
- Report result from process validation to Klarity.