Supplier Shipment Label Requirement

1.0 PURPOSE

The purpose of this procedure is to specify supplier labeling requirement for components, sub-assemblies, and assembled products.

2.0 SCOPE

This procedure is applicable to shipments from suppliers providing parts, materials, or services to Creation Technologies.

3.0 DEFINITIONS

Barcode – Code in the form of numbers and a pattern of parallel lines containing shipment information to identify a product.

Supplier – An organization that provides parts, materials, assemblies, systems, or services purchased by Creation. This includes sub-contractors, distributors, brokers, original equipment manufacturers, etc.

4.0 FUNCTIONS RESPONSIBLE FOR THIS PROCEDURE/ROLES

The functions listed below have responsibilities detailed in this procedure:

- **Procedure Owner:** Senior Director of Global Quality
- **Procedure User:** Supplier Chain, Supplier, Incoming Receiving Inspector
  - Supply Chain is responsible for communicating the requirements to the supplier.
  - Supplier is responsible for complying with the requirements of this document.
- **Contributors:** Incoming Receiving
  - Incoming Receiving/Supplier Chain feedback required component labels meet or exceed this requirement.

5.0 TRAINING

Course Code: COM_SC_SOP_0037

The process owner and document author are considered trained by default because of their contribution in writing and reviewing/approving the document.

Procedure users should be trained on the major revisions of this procedure before executing their task.

Contributors do not require formal training, but the procedure users are responsible for informing the contributor of their requirement when they are engaged in their contribution.

6.0 EQUIPMENT, MATERIALS, SUPPLIES

Label, label printer

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7.0 PROCEDURE

Note: *Unless otherwise specified by the customer, labels should be as described below.*

7.1 Label Characteristics

It is recommended to use white label and black ink.

7.2 Items shown on below format should be applied to shipment label.

- Creation Customer Part Number (if applicable), this PN is used for Creation's customer. Suppliers may apply Creation's CPN if available.
- Special Instruction (if applicable)

7.3 Barcode requirement

Content should be included as both barcode and human readable font.

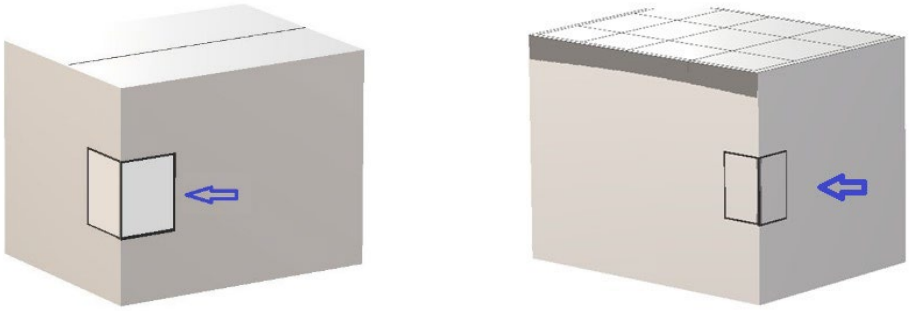
Preferences and Recommendations

- Code 39 is the preferred font for barcodes.
- Width of the narrow line is not recommended to be less than 0.0066 inches (0.167mm)
- Ratio of Wide bar width to Narrow bar width recommended to be a minimum of 2.5.
- Barcode height is recommended as minimum 0.20 Inches (5.08mm)
- Quiet zones before and after each barcode are recommended be minimum of 0.25 Inch (6.35mm)

7.4 Place the package label on the outermost level of box/pallet containing the components. Apply the label so that it does not interfere with the original manufacturer label.

7.5 Location

Creation prefers two duplicated package labels placed in adjoined corner of the box as shown. Ensure at least one label is visible when palletized.



7.6 Duplicate labels

For parts where a label cannot be applied to the final carrier such as Moisture Sensitive Package (MSP), affix duplicate labels placed on the immediate packaging (ESD bag/Moisture proof bag, box, etc.). One of the two labels should be peelable or removable to facilitate reapplication to contents after opening the package. If the label cannot be applied due to space, it can be applied to the next higher-level packaging (i.e. box, bag).

This will apply as well for material shipped on reels or other “individual” packaging, where labels are added to maintain product traceability.

7.7 Sample Label

For samples, an additional identification label is affixed next to the "material identification label". Samples can be packed in the same box as partial package of large goods, but clearly marked clearly marked on the outer package (partial package, sample label).

7.8 Rework Label

For reworked products, a ‘reworked products’ identification label is affixed next to the ‘material identification label.’ The reworked products can not be packed in the same box with the new products. Pack and label separately.

7.9 Serialized traceability

Components that require serialized traceability, the traceability label contains the serial number in barcode form and human readable font.

7.10 Regulatory label

Where applicable, regulatory and safety markings shall be applied as required by customer. This includes RoHS, UL, CCC, WEEE, Danger, Warning or similar labels.

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8.0 RISKS, OPPORTUNITIES, AND SAFETY

8.1 Risk

Without a supplier label requirement, there will be no consistency or standardization in the message or requirement we are sending to our suppliers.

8.2 Opportunities

Provides a standard method of labeling for shipments to Creation.

Consistency of labeling requirement for components, sub-assemblies, and assembled products shipped to Creation.

8.3 Environmental Health & Safety

Paper ripper/cutter health risk

9.0 EXCEPTION AND DEVIATION

Conditions Allowed	Action Required
If a requirement of this procedure cannot be implemented in a timely manner or it needs to be delayed from its schedule or if they are skipped or changed for a reason.	Please inform Creation immediately
If this procedure cannot be implemented by the effective date	Temporary Deviation will be documented using C-0003545 form

10.0 REFERENCED DOCUMENTS

Parent Document: C-0002890 Supplier Quality Requirements

10.1 Standard and Regulatory Requirements

Standard/Regulation #	Clause #	Document Name
FDA 21 CFR Part 820	Clause 45	Quality System Regulation – Medical Devices
ISO13485	4.2.3 Medical device file	Quality Management System – Medical Devices

10.2 Related documents

Document #	Document Name
C-0003545	Process/procedure temporary deviation form

11.0 KEYWORDS

Label; Barcode; Shipment; Supplier

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APPROVALS

See DocBank workflow approval

HISTORY OF CHANGES

Revision	Authored/ Revised by	Section # Changed	Summary of the Changes	Reason for the Change	Issue Date (YYYY MM DD)
0	Echo Lu		Initial release of C-0003229, Supplier Shipment Label Requirement		2022-07-22
A	Emmanuel Garcia	1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0 9.0	Reorganized entire document, revised, and combined sections for better flow and clarity	Overall improvement, reduce redundant sections and text. Refined language and clarification between requirement and guideline.	2025-05-02