



Q-CODE 3T QUALITY REQUIREMENTS

The following are the quality requirements for product purchased under Q-code Q3T. Please reference the Plexus Supplier Quality Manual [DCS 10503](#) for additional details and purchasing requirements. Unless a written waiver is received from Plexus, the supplier agrees to abide by the quality requirements listed below.

1ST SHIPMENT - THE DOCUMENTATION AND QUALITY REQUIREMENTS FOR THE INITIAL SHIPMENT AND/OR THE FIRST SHIPMENT AFTER ANY CHANGES HAVE BEEN MADE, ARE AS FOLLOWS:

- A. **First Article Inspection Report** - All dimensions, features and notes must be within print tolerance. Any which is not within print specification must be approved by Plexus in writing before product can be shipped. The FAIR must be complete with a bubble drawing and include the requirements as listed in the Plexus Supplier Quality Manual [DCS 10503](#).
- B. **Certificate of Compliance** - Must be titled as such and include a statement of compliance to all applicable specifications (statement is not required to list, but shall cover all the applicable specifications such as drawing, PO, customer specifications, UL, etc.). It also must include the following information for traceability:
- Name of Supplier (if different than the actual Manufacturer/OEM/OCM)
 - Plexus part number ordered on the Plexus PO
 - EC level or Revision level as specified on the Plexus PO for the Plexus part number ordered
 - Quantity Shipped
 - Plexus PO number
 - Name of Manufacturer/OEM/OCM
 - Manufacturer's/OEM's/OCM's Part Number
 - The Manufacturer/OEM/OCM Lot numbers or Date Codes (both are preferred) for each shipment. Certificates and packing slip must contain each lot and/or date code.¹
 - Location or place of manufacture
 - If the product has a shelf life, the manufacturer or cure date, batch number, the shelf life and expiration date must be included (note: the remaining shelf life must be greater than 50% of the stated shelf life). Any special handling and/or storage requirements must also be included
 - Name and title of supplier representative certifying the product
- C. **Material Certification** - A certification that the material used to manufacture the product is compliant to the following:
- i. RoHS compliance
 - ii. REACH compliance
 - iii. Statement shall include a specific reference that the product is not made with the following materials/substances:
 - Natural rubber latex
 - California Proposition 65 (Prop65) content
 - Substances that are carcinogenic, mutagenic or toxic to reproduction (CMR) content
 - Bisphenol A (BPA) content
 - Phthalates content
 - Transmissible Spongiform Encephalopathy (TSE)
 - Bovine Spongiform Encephalopathy (BSE)

The certification must also include the following:

- A statement specifying compliance to all applicable specifications.

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- The drawings and specifications
- The requirements of the specific PO

D. **Packaging Requirements** - All cartons, required documentation, labels, packaging and packing slips should have the Plexus part number, EC level or revision (if applicable), date code(s), quantity, and P.O. number listed on them. If this information is not included the documentation must be Traceable to the shipment of parts and all the other paperwork/certifications.

Shipments of multiple lot and/or date codes must be identified separately on the COC with the actual quantity shipped for each. Each lot and/or date code shall be independently packaged (i.e., no mixed lot/date codes within a package: reels, trays, tubes, bags, etc.).

¹ The minimum-required date code format shall identify the 2-digit workweek, 2-digit year (WWYY). If the component marking contains a lot and/or date code, then those markings must be traceable to the COC.

The above listed required documentation must be submitted with each shipment. Shipments received without the completion and proper execution of these Quality Requirements is considered non-conforming and Plexus reserves the right to return to the supplier at the supplier's expense.

ALL SHIPMENTS - THE DOCUMENTATION AND QUALITY REQUIREMENTS AS LISTED BELOW ARE REQUIRED WITH EACH SHIPMENT

A. **Certificate of Compliance** - Must be titled as such and include a statement of compliance to all applicable specifications (statement is not required to list, but shall cover all the applicable specifications such as drawing, PO, customer specifications, UL, etc.). It also must include the following information for traceability:

- Name of Supplier (if different than the actual Manufacturer/OEM/OCM)
- Plexus part number ordered on the Plexus PO
- EC level or Revision level as specified on the Plexus PO for the Plexus part number ordered
- Quantity Shipped
- Plexus PO number
- Name of Manufacturer/OEM/OCM
- Manufacturer's/OEM's/OCM's Part Number
- The Manufacturer/OEM/OCM Lot numbers or Date Codes (both are preferred) for each shipment. Certificates and packing slip must contain each lot and/or date code.¹
- Location or place of manufacture
- If the product has a shelf life, the manufacturer or cure date, batch number, the shelf life and expiration date must be included (note: the remaining shelf life must be greater than 50% of the stated shelf life). Any special handling and/or storage requirements must also be included
- Name and title of supplier representative certifying the product

B. **Material Certification** - A certification that the material used to manufacture the product is compliant to the following:

- iv. RoHS compliance
- v. REACH compliance
- vi. Statement shall include a specific reference that the product is not made with the following materials/substances:
 - Natural rubber latex
 - California Proposition 65 (Prop65) content
 - Substances that are carcinogenic, mutagenic or toxic to reproduction (CMR) content



- Bisphenol A (BPA) content
- Phthalates content
- Transmissible Spongiform Encephalopathy (TSE)
- Bovine Spongiform Encephalopathy (BSE)

The certification must also include the following:

- A statement specifying compliance to all applicable specifications.
 - The drawings and specifications
 - The requirements of the specific PO

C. **Packaging Requirements** - All cartons, required documentation, labels, packaging and packing slips should have the Plexus part number, EC level or revision (if applicable), date code(s), quantity, and P.O. number listed on them. If this information is not included the documentation must be Traceable to the shipment of parts and all the other paperwork/certifications.

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PRODUCT CHANGE NOTIFICATION

Product or Process change notification requests (PCNs) shall be submitted to pcns@plexus.com, please reference the details of our PCN policy and requirements in the Plexus Supplier Quality Manual [DCS 10503](#).

REVISION HISTORY

REV	RELEASE DATE	ORIGINATOR	DESCRIPTION OF CHANGE(S)	REASON FOR CHANGE(S)
A	Draft	Paul Gettins	New	Initial Release
B	04 May 18	Daniel Crouse	Add PCN Language	Process Change Notification
C	08 Nov 22	Paul Gettins	Additions to the list for the Material cert	Update to include patient contact material substances prohibition