

**REVISION HISTORY**

<u>REV</u>	<u>DATE</u>	<u>ORIGIN</u>	<u>REASON FOR CHANGE(S)</u>
A	3/20/02	Dorothy Woodington	New
B	7/22/02	Scott M. Ubl	New format
C	5/04/18	Daniel Crouse	Added PCN language

**Q-CODE Q3B QUALITY REQUIREMENTS****For Medical products with raw material traceability**

The following are the quality requirements for product purchased under Q-code Q3B. Unless a written waiver is received from Plexus, the supplier agrees to abide by the quality requirements listed below.

**1<sup>st</sup> Shipment/EC change**-The documentation and quality requirements for the 1st shipment are as follows:

- A. First Article Inspection Report (FAIR)- All dimensions must be within print tolerance. Any dimension which is not within print specification must be approved by Plexus in writing before product can be shipped.
- B. Critical to Function Inspection Report (CTF) - All CTF dimensions as indicated per print, must be within print tolerance. Any dimension which is not within print specification must be approved by Plexus in writing before product can be shipped.
- C. Certificate of Compliance (COC). - This must include the shipment quantity and quantity of each production lot shipped when they are different.
- D. Material Certificate and Traceability - This must list all material (i.e. raw material, color additives, etc...) used in the product with the material lot number, manufacturer and part number for traceability.
- E. All cartons, packing slips and C.O.C.'s must have part number, EC level or revision, quantity and P.O. number listed on them.

**Subsequent Shipments** - The documentation and quality requirements for all subsequent shipments will be as follows:

- A. Critical to Function Inspection Report (CTF) - All CTF dimensions, as indicated per print, must be within print tolerance. Any dimension which is not within print specification must be approved by Plexus in writing before product can be shipped.
- B. Certificate of Compliance - This must include the shipment quantity and quantity of each production lot shipped when they are different.
- C. Material Certificate and Traceability - This must list all material (i.e. raw material, color additives, etc...) used in the Product with the material lot number, manufacturer and part number for traceability.
- D. All cartons, packing slips and C.O.C.'s must have part number, EC level or revision, quantity and P.O. number listed on them.

The above listed documentation must be submitted with each shipment as specified. Any shipment received without this documentation will be considered defective.



**Product change notification**

Upon acceptance of conforming product, documentation, and the requirements of this Q-code, the supplier's manufacturing process shall be considered "qualified". All changes require written approval from Plexus prior to implementation. Product or Process change notification requests (PCNs) shall be submitted to [pcns@plexus.com](mailto:pcns@plexus.com).