



Q-CODE Q37K QUALITY REQUIREMENTS

The following are the quality requirements for product purchased under Q-code Q37K. 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 and resubmit appropriately for any product or process change.

The supplier shall refer to the Medtronic Product Level Quality Impact Assessment (PLQIA) for the part number being purchased to determine the Quality Impact Level of the part. The below table will then be used, along with the requirements that follow in this Q-code, to determine the applicable qualification requirements. (Note: the supplier should contact the Plexus buyer to obtain a copy of the PLQIA for the part number being purchased if one has not already been provided.)

Quality Impact Level	Data Type	Initial Qualification		
		Min Sample Size/Lot	Capability Assessment Required	Acceptance Criteria
Minor	Attribute	29	No	c = 0
	Variable	15	Yes	Ppk \geq 1.00
	100% ongoing	100%	No	c = 0
Negligible	Attribute	5	No	c = 0
	Variable	5	No	c = 0

QUALIFICATION

Before a product will be released for production, the supplier will be required to demonstrate the product meets specifications and has control of variation in order to reliably produce good product. The following steps and deliverables are required of the supplier. The supplier is required to submit the qualification documentation and receive approval from Plexus prior to shipping product.

- A. **First Article Inspection Report** - The supplier will perform a first article inspection including a measurement and acceptance of every characteristic, requirement and/or drawing note. This will be documented and submitted on a report for a minimum of 5 pieces. All dimensions must be within print tolerance. The FAIR must be complete and include the requirements as listed in the Plexus Supplier Quality Manual [DCS 10503](#). In addition, the FAIR must include the following: test facility name and location; date; test method and equipment used; person who collected or approved the data and signature.
- B. **Material Certification** - must include a list/BOM of all raw materials used with associated raw material certification or test data. If product is designated to comply with RoHS, REACH or similar material substance requirement, the appropriate certificate must also be included.
- C. **Capability Studies** - During the qualification run, the supplier will sample (using sample size identified in the table above) from an appropriate number of pieces that represent the distribution of the process. Using these samples, the supplier will perform a capability study on all Minor characteristics, and any supplier selected process control characteristics. The supplier's submission to Plexus will include: control charts; calculated values for X-bar and Sigma; charts showing the data distribution; Pp and Ppk values; all associated data; and reference to the software and revision used for the data analysis. The results must meet the Ppk requirements defined in the table above. This is not required if the characteristic is 100% ongoing inspected.



Note:

- Processes are not always double sided or normally distributed. In these cases a comparative measure and representation of Process Capability shall be recommended by the supplier and approved by Plexus.
- The supplier shall provide rationale if using sample size or number of lots less than the minimum (e.g. homogeneous materials where sample size may be 1 per lot, only a single lot will be purchased for the lifetime of the product, etc.)

- D. **Packaging and Labeling Documentation** - The supplier is required to evaluate, define, and document the packaging specifications and submit the specifications for approval to Plexus. The specifications shall be adequately defined to assure consistency in packaging methods and protection during the shipping and handling.

If the above qualification criteria is met, utilizing the defined processes, the supplier will be granted approval from Plexus and the product will be released for production builds. If any of the above criteria are not met, the supplier must notify Plexus and use the data to make the appropriate tool, sampling, measurement system and/or process corrections in order to re-execute the qualification successfully before concessions to this plan can be made. Any concessions made will require an alternative strategy with approval by the supplier and Plexus. This most commonly will include a 100% sampling of the measurement or use of a Poke Yoke device.

ALL SHIPMENTS

The following are the quality requirements for all shipments of purchased parts qualified per this Q-code. Unless a written waiver is received from Plexus, the supplier agrees to abide by the quality requirements listed below. The following steps and deliverables are required of the supplier:

- A. **Approved for Production** - the supplier must use the approved process (as defined in the qualification runs above) to manufacture and supply the part.
- 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, Plexus G9000-3, NFS, IPC 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
 - 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, with signature and date
- C. **Material Certification**



All cartons, required documentation, labels, packaging and packing slips must have the Supplier Name, Plexus part number, EC level or revision (if applicable), lot number or date code(s), quantity, and P.O. number listed on them.

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.

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	02Jun2021	Joyce Conn	New - Initial Release	N/A