



REVISION HISTORY

REV	DATE	ORIGIN	REASON FOR CHANGE (S)
A	27Sep2018	Bobby Schaefer	Released

Q-CODE Q37D QUALITY REQUIREMENTS

Medtronic Custom PPAP Level 4a

The following are the quality requirements for product purchased under the Q-code Q37D. Unless a written waiver is received from Plexus, the supplier agrees to abide by all the quality requirements as listed below.

All required quality documentation must be submitted through the Plexus Supplier Portal ([LINK](#)), reviewed, and approved prior to shipping to Plexus. If you do not have a log in, contact your Plexus Buyer for access. Instructions for uploading documents can be found on the Portal log in page.

First Shipment	Requirement
First Article Inspection Report on 3 pieces including conformance to all drawing notes, along with balloon drawing.	X
Process Failure Modes and Effects Analysis for finished assembly (Cover page and table of contents are sufficient to demonstrate evidence)	X Maintained at Supplier
Process Flow Diagram for finished assembly	X
Measurement System Analysis (a Gage R&R) for PC and Stop Sign dimensions at final assembly (P/T Ratio<30%, GR&R <30%, Attribute >80% is acceptable) ●	X
Test Results for outside processes, if applicable (i.e. plating or hardness, if not covered in the FAIR or certificates)	X
Lot/Date code traceability (see details on page 2)	X
Production Certifications (Material Certification and RoHS 2011/65/EU Certificate required and a REACH Declaration if available)	X
Preventative Maintenance Plan or process will be created and maintained by the supplier for the equipment used to assemble each part number. (Cover page and table of contents are sufficient to demonstrate evidence)	X Maintained at supplier
Electrical Testing Certificate – Any time a part or assembly has a specific electrical test requirement listed, it must be electrically tested. Proof of testing conformance to the testing requirement shall be provided by including the test data, a test stamp and/or a test certificate.	X
All stop sign dimensions are to be 100% measured on every part in the shipment and provided to Plexus. ●	X
Custom Checking Aids during assembly and final test of finished assembly (If used, provide a listing showing use and identification number)	X

*Notice: This document is considered "UNCONTROLLED" when it exists in any printed form.

See the Partner - Supplier section of the Plexus Web page for the current master of this Q-code.



Consecutive Shipments	Requirement
Certificate of Compliance – See below for C of C requirements	X
All stop sign dimensions are to be 100% measured on every part in the shipment and provided to Plexus. ●	X
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 approval from Plexus prior to implementation. Product or Process change notification requests (PCNs) shall be submitted to pcns@plexus.com.	X

Certificate of Compliance– Must include a statement of overall compliance to all **applicable** specifications (statement is not required to list but shall cover all applicable specifications such as: drawing, PO, customer specifications, etc.). In addition, the certificate of compliance must include the following traceability information:

- **RoHS compliant to EU Directive 2011/65/EU or higher.**
- REACH declaration, if available.
- Name of Supplier (if different than the actual OEM)
- Name of Manufacturer
- Manufacturer's Part Number
- The Lot Number and/or Date Code (both preferred, but date code at a minimum) for each shipment - COC and packing slip must contain each lot and/or date code¹
- Plexus part number ordered on the PO
- EC level or Revision level as specified on the PO for the Plexus part number ordered
- Plexus PO number
- Bar coding this information in 39 or 128 format is optional

All cartons, packing slips and certificates must have part number, EC level or revision, quantity and P.O. number listed on them.

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.

*Notice: This document is considered “UNCONTROLLED” when it exists in any printed form.
See the Partner - Supplier section of the Plexus Web page for the current master of this Q-code.