REVISION HISTORY

REV	DATE	ORIGIN	REASON FOR CHANGE (S)
A	02/20/2017	Scott Leffler	Released
B	06/07/2017	Steve VanScoyoc	Added REACH Declaration requirement
C	27Jun2017	Steve VanScoyoc	Added requirements for sub-components
D	10/19/2017	Sarah Smith	Added requirements for documents to be submitted through portal. Clarified w/ID # on the process control plan
E	05/03/2018	Sarah Smith	Admin change only to clarify requirements: Changed to table format, added in PCN notification

Q-CODE Q37A QUALITY REQUIREMENTS

Medtronic Custom PPAP Level 3

The following are the quality requirements for product purchased under the Q-code, Q37A. 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.

There are two options a supplier can select from when supplying product to the Q37A requirement. The chart below lists the requirements that must be met for the option selected. Consecutive shipments must follow the same option chosen for the first shipment of product.

		Option 1	Option 2
First Shipment		**W/Process Study**	**100% Inspection**
	First Article Inspection Report on 3 pieces including conformance to all drawing notes, along with balloon drawing. This includes any sub-components of this part. (Not required for Off The Shelf sub-components)	X	X
	Process Failure Modes and Effects Analysis	X	
	Process Flow Diagram	X	X
	Process Control Plan (Must address all PC and Stop Sign dimensions, and checking aids w/ID #)	X	
	Measurement System Analysis (a Gage R&R) for PC and Stop Sign dimensions (P/T Ratio <30%, GR&R <30%, Attribute >80% is acceptable)	X	X
	Test Results for outside processes (i.e. plating or hardness, if not covered in the FAIR or certificates)	X	X
	Initial Process Studies (Required for all stop sign dimensions)	X	
	Initial Process Studies for all sub-components of any assembly (Required for all stop sign dimensions)	X	
	When capability has been demonstrated, the supplier shall track PC dimensions via SPC charting, or implement an AQL sampling plan	X	
	Lot/Date code traceability (see details on page 2)	X	X
	Production Certifications (Material Certification and RoHS 2011/65/EU Certificate required and a REACH Declaration if available)	X	X
	Preventative Maintenance Plan or process will be created and maintained by the supplier for the equipment used to manufacture each part number.	Maintained at supplier	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	X
	All stop sign dimensions are to be 100% measured on every part in the shipment and provided to Plexus. This includes any sub-components of this part.		X
	Custom Checking Aids (if used provide a listing showing use and identification number)		X

Consecutive Shipments		**Option 1**	**Option 2**
	Certificate of Compliance – See below for C of C requirements	X	X
	All stop sign dimensions are to be 100% measured on every part in the shipment and provided to Plexus. This includes any sub-components of this part.		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	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, Plexus G9000-3, IPC specifications, etc…). It also must include the following traceability information:

- **RoHS compliant to EU Directive 2011/65/EU or higher.**
- ***If the verification approach is used, then all shipments shall have the 100% stop sign data provided.***
- 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 code [1]
- 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.

- For all shipments of **Printed Circuit Boards,** the requirements of Q22A must also be fulfilled.

[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. 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.).

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.