REVISION HISTORY

REV	DATE	ORIGIN	REASON FOR CHANGE (S)
A	10/10/2018	Sarah Smith	Released

Q-CODE Q37E QUALITY REQUIREMENTS

Medtronic Custom PPAP Level 2A

The following are the quality requirements for product purchased under the Q-code, Q37E. 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.

On the first shipment - The documentation and quality requirements for the first shipment will be as follows:

- 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 parts)
- Process Control Plan by commodity
- Lot/Date code traceability (see details below)
- Production Certifications (Material Certification and RoHS 2011/65/EU Certificate required and a REACH Declaration if available)
- Preventative Maintenance Plan or process will be created and maintained by the supplier for the equipment used to manufacture each part number. (Not a deliverable)
- 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.

All Shipments – The documentation and quality requirements as listed below are required with each shipment:

- 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.**
  - 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.

- Product Change Notifications (PCNs) pertain to components which have been identified on the Product Source Control Document.

[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.).