## 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 | 06/27/2017 | 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 the wording on Process Control Plan and Added PCN statement at the bottom |
| F | 04/13/2023 | Kevin Garrity | Added RoHS and REACH compliant language, location of manufacturer, added first and all shipment requirements, added Appendix 1 |
| G | 11/13/2023 | Kevin Garrity | Updated Medtronic specific information link |

## Q-CODE Q37 QUALITY REQUIREMENTS
### Medtronic Custom PPAP Level 2

The following are the quality requirements for product purchased under the Q-code, Q37.  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.

## 1      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
➢ Process Flow Diagram – As applicable.  Will be required when a change affects process flow or Plexus customer requests during their review of PCN.
➢ Process Failure Modes, and Effects Analysis – As applicable.  Will be required if Plexus customer requests during their review of PCN.
➢ Lot/Date code traceability[1] (see details below in all shipments certificate of compliance)
➢ Production Certifications (Material Certification and RoHS 2011/65/EU, (EU) 2015/863 Certificate and a REACH (EC) 1907/2006 and directive 2006/121/EC Declaration required or most recent SVHC list revision date declaration (but not older than 1 year from the most recent list))
➢ When process capability has been demonstrated, the supplier shall track PC dimensions via SPC charting, or implement an AQL sampling plan.  The requirement for process capability may be waived at the discretion of the PPAP Owner if the supplier is conducting ongoing 100% inspection for that applicable dimension. For more information, see Medtronic Specific Information for further information.
➢ Process Validation (IQ, OQ, PQ) as required and must be documented. See Appendix 1 for validation guidelines. As Applicable
➢ 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 unless a component change occurs related to a Preventative Maintenance update)
➢ Measurement System Analysis (a Gage R&R) for PC, CTF, and Stop Sign dimensions (P/T Ratio <30%, GR&R <30%, Attribute >80% is acceptable). (If applicable please include Accuracy, Precision, Resolution Gage R&R requirements). For more information, see Medtronic Specific Information for further information.
➢ 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.
➢ Test method validation – As applicable any time that a protocol and report is required for a MSA. For more information, see Medtronic Specific Information for further information.

## 2      ALL SHIPMENTS

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

- <u>Certificate of Compliance</u> – 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 as amended by commission delegated directive (EU) 2015/863 or higher.
    - REACH compliant to Regulation (EC) 1907/2006 and directive 2006/121/EC or most recent SVHC list revision date declaration (but not older than 1 year from the most recent list).
    - Name of Supplier (if different than the actual OEM)
    - Name of Manufacturer
    - Manufacturer's Part Number
    - Location or place of Manufacturer
    - 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.).

## 3      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.

## 4      MEDTRONIC SPECIFIC INFORMATION

Additional details specific to Medtronic requirements can be found at the following link: Medtronic PPAP Details

**APPENDIX 1**

4.1     Validation Documentation for the IQ, OQ AND PQ METHODOLOGY
Any recommendations for format of validation documents are not mandatory, but consistency, completeness and accuracy in the documentation are required.

4.2     Validation Protocols
A protocol is a written plan that describes how to conduct qualification/validation activities, the set process or methods, and define acceptance criteria. All protocols must be reviewed and approved for technical content and regulatory compliance by the supplier and Plexus prior to execution.

All protocols shall be controlled and contain the following information:
- Title Page.
- History and Document Revision Control.
- Table of Contents.
- Approval Record: An approval sheet with name, signature, and date of each Validation Team member must be part of the Protocol.
- Personnel Identification Form: If anywhere within validation package a person uses initials only to sign a document (such as test records), a table or form that provides initials and signature cross-reference for each person using their initials needs to be included.
- Purpose: Provide a clear, concise statement describing the intent of the Qualification.
- Scope: Identifies the process/system to be Qualified.
- Assumptions/Strategies: State any assumptions or strategies that pertain to the qualification.
- General Description of Process or System: Description of the process/system, equipment location within the facility and the site location where the validation activities will occur.
- References: List the applicable regulatory standards, equipment manuals and specifications, procedures, software versions, and other documents that are needed to plan the Qualification.
- Definition.
- Personnel/Responsibilities: Record title/function of any internal or external personnel required to complete the Qualification tasks.
- Test and Acceptance Criteria: List the requirements of the items to be verified, including pass/fail criteria, to conclude that the results of the given protocol are acceptable. Test and Acceptance criteria shall be traceable to a customer, industry requirements or manufacturer specifications as applicable. Otherwise engineering characterization or DOE studies should be conducted to make the determination
- Procedure: Details qualification activities based on product/process requirements:
  - Determine what to verify/measure
  - Determine how to verify/measure
  - Determine how many to verify/measure
  - Define acceptance/rejection criteria
  - Define required documentation for collecting and reporting data

*Note:  Once the validation team approves the protocol, the protocol can only be revised in a controlled manner.*

4.3     Validation Sampling Plan
Sampling plans, when used, shall be based on a valid statistical rationale. Plexus will provide the minimum Sampling plan to be used for validations.

4.4     Validation Report
At the conclusion of executing any formal protocol a validation report is required. The validation report is an overview of the respective protocol and actual validation activities.

A validation report shall contain the following:
- Purpose
- Scope
- General Description of System/Process
- Training and the verification of training records
- References (if required)
- Review of Discrepancies (if required)

- Acceptance Criteria
- Gage R and R or Verification of Measurement System with data
- Capability Statistics and Study with data
- Verification/inspection data
- Conclusions, include validation activities results summary
- Rationale for acceptance and conclusions (if required)
- Statement Authorizing Release of the System/Process
- Approval signatures

Validation reports for each respective validation protocol stage must be reviewed and approved prior to beginning the execution of the next step.