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 to table format, added in PCN notification
F	04/13/2023	Kevin Garrity	Added RoHS and REACH compliant language, location of manufacturer, additional first and consecutive shipment requirements added
G	08/31/2023	Kevin Garrity	Removed the paragraph about options as the options have been eliminated
H	11/14/2023	Kevin Garrity	Updated Medtronic specific information link
I	12/06/2023	Kevin Garrity	Added "if applicable" requirement to First Shipment section for CTF/PC/stop sign dimensions.

Q-CODE Q37B QUALITY REQUIREMENTS

Medtronic Custom PPAP Level 4

The following are the quality requirements for product purchased under the Q-code, Q37B. 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	Required
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
Process Failure Modes and Effects Analysis	X
Process Flow Diagram	X
Process Control Plan (Must address all PC , CTF (Critical to Function), and Stop Sign dimensions, and checking aids w/ID #)	X
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.	X
Test Results for outside processes (i.e. plating or hardness, if not covered in the FAIR or certificates) – All certifications must address drawing note requirements	X
Initial Process Studies (Required for all PC, CTF, and stop sign dimensions). For more information, see Medtronic Specific Information for further information.	X
Initial Process Studies for all sub-components of any assembly (Required for all PC, CTF, and stop sign dimensions). For more information, see Medtronic Specific Information for further information.	X
Process Validation (IQ, OQ, PQ) as required and must be documented. *See Appendix 1 for validation guidelines.* (Index >1.33 Cpk is acceptable, on minimum of 30 sample pieces). When capability has been demonstrated, the supplier shall track PC dimensions via SPC charting, or implement an AQL sampling plan.	If applicable
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.	X
Lot/Date code traceability (see details under Certificate of Compliance on page 2)	X
Production Certifications (Material Certification and RoHS 2011/65/EU, (EU) 2015/863 Certificate and 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)) – Must show evidence to drawing note requirements.	X

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)	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. This includes any sub-components of this part. This is only applicable if the supplier has not shown process capability.	If applicable
Custom Checking Aids (if used provide a listing showing use and identification number)	If applicable
Test Method Validation – Applicable any time that a protocol and report is required for a MSA. For more information, see Medtronic Specific Information for further information.	If applicable
Consecutive Shipments	**Required**
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. This includes any sub-components of this part. Applicable If supplier has not shown process capability.	If applicable
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, 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.).

1 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.

2 MEDTRONIC SPECIFIC INFORMATION

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

3 APPENDIX 1

3.1 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.

3.2 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.*

3.3 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.

3.4 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.