Medtronic Custom Requirements

Q-Code (Q37C) Quality Requirements

The following are the quality requirements for product purchased under the Q-code, Q37C. Unless, a written waiver is received from Plexus, the supplier agrees to abide by all the quality requirements as listed below.

The chart below lists the requirements that must be met.

Requirements	First shipment	Subsequent shipments
First Article Inspection (FAI) Report on a minimum of one piece including conformance to all drawing notes, along with balloon drawing. All dimensions must be within print tolerance. Any dimension which is not within print specification must be approved by Plexus in writing before product can be shipped. The FAIR must be complete and include the requirements as listed in the Plexus Supplier Quality Manual DCS 10503 This includes any sub-components of this part. (Not required for Off The Shelf sub-components)	X	Only needed if process or design changes are made. See change notification requirement below.
Process Flow Diagram, including materials contacting components (e.g., cutting fluids, coolants, cleaning agents, gloves, etc.)	X	
Process FMEA, including Rating tables for Severity, Occurrence and Detection.	X	Full-first article inspection is required, unless otherwise stated that partial FAI is acceptable based on change.
Process Control Plan including process steps where inspection will occur. Inspection steps shall include all CTQs, equipment or tooling required, sample size, frequency of inspection and reaction plan if parts are non-conforming.	X	
Measurement System Analysis (MSA or Gage R&R) for critical dimensions denoted as CTQ, , C, or measurement points (MP) Variable MSA: • Setup: Minimum 2 appraisers, 5 samples, 2 replicates • Both requirements listed below must be met: ○ (# of appraisers) x (# of samples) x (# of replicates – 1) ≥ 30 ○ Variable MSA: % Tolerance < 30% and Number of Distinct Categories ≥3 Attribute MSA: • Minimum of 20 parts • Attribute MSA: ≥ 80% for “Within Appraisers”, “Each Appraiser vs. Standard”, “Between Appraisers”, and “All Appraiser vs. Standard”)	X	
Traceability: Lot/Date code traceability Process documentation is traced to all levels of manufacture. At a minimum, this includes operator performing the operation and date performed, shift (as applicable), Manufacturing work instructions used, and use of validated equipment and identification of equipment used, BOM/drawing revision and configuration, resolution of any discrepancies, and Record of any Rework performed.	X Process documentation to be maintained at supplier, and available upon request. Not required to be	X Process documentation to be maintained at supplier, and available upon request. Not required to be supplied with parts.

	supplied with parts.	
Production Certifications (Certificate of Compliance, Material Certification and RoHS 2011/65/EU Certificate required and a REACH Declaration if applicable). See detailed notes on Certificate of Compliance requirements below.	X	X
Equipment/Process qualification evidence: • Installation Qualification (IQ) including equipment installation per manufacturer's recommendation • Implementation of Calibration and Preventative Maintenance Plans for equipment used to manufacture and inspect production parts If applicable, process validation documentation (OQ/PQ) for non-verified processes.	X IQ documentation submitted for review with/prior initial production shipment	Maintained at supplier unless changes are made. See change notification requirement below
All critical dimensions denoted as CTQ, , , C, or measurement points (MP) are to be 100% measured on every part in the shipment (variable data preferred over attribute, Pass/Fail) and provided in Excel file or equivalent spreadsheet form upon request. This includes any sub-components of this part. Critical dimensions must be measured with the tool/equipment used for the corresponding MSA/GRR study.	X (Inspection report to be shipped with parts)	X (Inspection report to be shipped with parts)
Custom Checking Aids (if used provide a listing showing use and identification number)	Maintained at supplier	Maintained at supplier

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.**
- 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.

[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. Product or process changes include modification of manufacturing processes (i.e. manufacturing sequence change, addition/removal of steps), materials/agents that contact the product during manufacturing, or inspection method/equipment etc.

REVISION HISTORY

REV	RELEASE DATE	ORIGINATOR	DESCRIPTION OF CHANGE(S)	REASON FOR CHANGE(S)
A	08/21/2018	Santhosh Kattookaran		New per Medtronic
B	10/17/2018	Santhosh Kattookaran		Updated to CTF designations
C	08/30/2019	Santhosh Kattookaran		Update MSA requirements to align with Medtronic Louisville internal procedure; update control plan details, CTQ symbols, and lot/date code requirements; add requirement to maintain CTQ inspection data in spreadsheet format
D	07Apr2021	Santhosh Kattookaran	Update MSA requirements to; add process information detail to traceability requirement. Update the format of table to increase clarity on what is require for first shipment vs. subsequent shipments Added clarification for change notification to include example changes that need notification Add equipment IQ and process validation requirement.	Align with Medtronic Louisville internal procedures and add clarification for PCN expectations. Use the new Q-code format/template.