REVISION HISTORY

REV	DATE	ORIGIN	REASON FOR CHANGE (S)
A	18Nov2020	Santhosh Kattookaran	New per Medtronic

Q-CODE Q37G QUALITY REQUIREMENTS

Special Medtronic requirements

The following are the quality requirements for product purchased under the Q-code, Q37G. 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.

	First Shipment	First shipment	Subsequent shipment
	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	Only needed if process or design changes are made.
	Measurement System Analysis (a Gage R&R) for critical dimensions denoted as CTQ or measurement points (MP) Variable MSA: ➢ Both requirements listed below must be met: 1. Minimum 2 appraisers, 5 samples, 2 replicates 2. (# 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	
	Test Results for outside processes (i.e. plating or hardness, if not covered in the FAIR or certificates)	X	X
	Lot/Date code traceability	X	X
	Production Certifications (Material Certification and RoHS 2011/65/EU Certificate required and a REACH Declaration if applicable)	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	
	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. This includes any sub-components of this part. Critical dimensions must be measured with the tool/equipment used for the corresponding MSA study.	X	X
	Custom Checking Aids (if used provide a listing showing use and identification number)	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 or higher, if applicable.
- Name of Supplier (if different than the actual OEM)
- Name of Manufacturer
- Manufacturer's Part Number
- The Lot Number and Date Code for each shipment - COC and packing slip must contain each lot and 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] Shipments of multiple lot and date codes must be identified separately on the COC with the actual quantity shipped for each. Each lot and 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 changes in manufacturing processes including changes to the sequence of the steps or manufacturing step details.