SOP Reference #: QS016

Operation/Task:	Medtronic IFU Requirements			Equipment:	None
Owner:	Quality Manager	Date Created: Revision History:	2/14/2022 See last page	Department:	Quality Systems

ALERTS (see below): Critical Step ◆ Quality Check ☑ Tip ☺ Team Safety ✚

Purpose: This SOP/work instruction describes specific requirements for producing work for customer Medtronic

Step #	Alerts	Step Description - "What to Do"	"How to Do it"	"Why to Do it"
1		Enhance inspection and QC techniques as required for customer Medtronic	Include additional production requirements for Medtronic IFU products	To achieve 100% conforming product
2	◆	Offset press requirement for QC pulls is increased	Press requirement is double standard press pull frequency. Up to 5 per hour depending on press speed.	Additional QC pulls narrow field for non-conforming sheets.
3	◆	Prepress requirement for bar code placement	Bar codes as close to press sheet gripper as possible and on first side impression when imposed.	Reduce possibility of bar code dot gain
4	◆	Finish requirements	1. Inspection of 3 sides of stitched material lifts 2. Fan parts prior to loading stitcher pocket to inspect bar code. 3. Test bar codes at packaging station 4. Perform line clearance process for each version included in a production run	Remove non-conformances at stitcher Ensure bar codes are clean Ensure bar codes can be read Keep versions separate and product accurate.

5	◆	Inspection requirement and trigger for 100% inspection	Inspection of finished product must follow the requirements of the established sampling technique. See QS017 for requirements. If during the sampling process, a single non-conforming part is found, the sample must be doubled and inspected with no additional non-conforming parts found in order to pass inspection. If more than one non-conforming part is found during sampling, either in the initial inspection or the expanded sample, a 100% inspection is triggered for the discovered non-conformance. This means all parts of the job must be inspected for conformance and a count kept of all parts discovered to be non-conforming. If the 100% inspection is triggered, alert the department supervisor or quality manager. The supervisor or quality manager will supervise the inspection.	This technique is an accepted protocol for sampling and inspection. The goal is 100% conformance so the standard is severe. The expansion of the sample is used to determine the breadth of the non-conformity The supervisor or quality manager may determine that the inspection may be suspended based on finding no additional non-conforming parts after inspecting 20% of the total lot.
6	◆	Project Management	Record customer requirements in MIS system database for customer Medtronic	Requirements are available to print on production documents specific to customer.

7	◆	Vendor Management	ENPOINTE will communicate any changes in product products via the SCR (Supplier Change Request) Portal, which is used to manage and evaluate any changes made to supplier processes, materials, formulations, etc. https://wwwp.medtronic.com/changerequest/public/landingPage Add the Medtronic Affected Facilities and the Operating Unit affected for the part numbers, which is Peripheral Vascular & Endovenous for our Tijuana Nellcor site. **Note:** Every site impacted by the change must be added, and all affected part numbers must be included for each site.	To communicate material composition to Medtronic to proper validation or traceability, which constitutes traceability parts escape.

Notes: This process is invoked upon behalf of customer.
Definitions: QS016 is a quality system SOP defining the sampling technique deployed at ENPOINTE.

Revision History	**Description of Changes**	**Requested by**	**Date**
Original	First posting to intranet	Dean Milinkovich	3/7/2022
Rev. 1	Added instruction for 100% inspection requirement	Dean Milinkovich	6/22/2022
Rev. 2	Added Step #7, Vendors are required to notify Medtronic with any product changes	Danette Colin	3/23/26