



DOCUMENT TYPE:  
QUALITY ASSURANCE SPECIFICATION



DOCUMENT NUMBER: QAS 717 ETAL

DCO NUMBER: 019005

ISSUE DATE: 1-28-19

EFFECTIVE DATE: 1-28-19

PAGE: 1 of 6

☒ PACKAGING

☐ MANUFACTURING

☐ MOLDING

ITEM: SUTURE REMOVAL KITS – 4 LANES TOOLING

BUSSE CATALOG #: REFER TO DHR

DESCRIPTION: REFER TO DHR

PACKING: REFER TO DHR AND MANUFACTURING INSTRUCTIONS

SAMPLING INSTRUCTIONS: **SAMPLE SIZES MUST BE MET FOR EACH SHIFT/WORK ORDER**

SAMPLING FREQUENCY: REFER TO SOP 10-02

UNIT	(VISUAL):	ANSI/ASQC- Z1.4-2003 (R 2013), SINGLE NORMAL LEVEL S-4-EVERY TWO HOURS	
	(FUNCTIONAL):	SEAL STRENGTH:	ONE CYCLE EVERY FOUR HOURS
		PIN HOLE TEST:	ONE CYCLE EVERY FOUR HOURS
		PEEL APART TEST:	TWO CYCLES EVERY TWO HOURS
		BARCODE VERIFICATION:	ONE CYCLE EVERY FOUR HOURS
	(DIMENSIONAL):	N/A	

DISPENSER:	(VISUAL):	FOUR DISPENSERS PER INSPECTION-IF APPLICABLE REFER TO THE DHR
	(FUNCTIONAL):	N/A
	(DIMENSIONAL):	N/A

SHIPPING CONTAINER:	(VISUAL):	TWO CASES EVERY TWO HOURS
	(FUNCTIONAL):	N/A
	(DIMENSIONAL):	N/A

**NOTES:**

- 1) IF THE JOB/WORK ORDER DOES NOT RUN A FULL SHIFT FULL SAMPLE SIZE WILL NOT BE PERFORMED; ONLY THE QUANTITY REQUIRED PER INSPECTION SHOULD BE PERFORMED.
- 2) IF VISUAL SAMPLE SIZE IS LESS THAN 20 PIECES; A MINIMUM OF 20 PIECES SHOULD BE INSPECTED
- 3) TOLERANCE FOR SAMPLING IS +/- 30 MINUTES.

**CRITICAL DEFECTS**

***AQL not applicable: any defect at any sample size is cause for rejection.***



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## DOCUMENTATION

1. Incorrect/Incomplete documentation
2. Missing documents

## UNIT

### VISUAL INSPECTION

3. Incorrect/Incomplete components
4. Missing components
5. Improper placement of component in package- refer to manufacturing instructions
6. Incorrect print mat – refer to DHR for print mat format number
7. Incorrect/ Illegible lot#/ cat #
8. Illegible print/ missing print
9. Missing/ incorrect expiration date- if applicable refer to DHR
10. Incorrect ink color – refer to DHR
11. Open seals
12. Channels/Voids in seal
13. Peel Here flap sealed
14. Miscellaneous Critical Defect

### FUNCTIONAL INSPECTION

15. Seal strength less than 0.5 lbs – Refer to TM 004-Or TM 113
16. Does not pass pin hole test – Refer to TM 001
17. Does not pass Peel Apart Test- Refer to TM 003

### DIMENSIONAL INSPECTION

N/A



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## DISPENSER

### VISUAL INSPECTION

- 18. Incorrect count
- 19. Incorrect component
- 20. Incorrect label
- 21. Incorrect missing cat#/lot #
- 22. Incorrect packing into dispenser- refer to manufacturing instructions

### FUNCTIONAL INSPECTION

N/A

### DIMENSIONAL INSPECTION

N/A

## SHIPPING CONTAINER

### VISUAL INSPECTION

- 18. Incorrect shipping container
- 19. Incorrect packing- refer to manufacturing Instructions
- 20. Missing/ incorrect lot number/cat #
- 21. Incorrect/ missing expiration date-If applicable-Refer to DHR
- 22. Incorrect label – refer to DHR for current format # - if applicable
- 23. Incorrect tape color-Refer to SOP 09-98-If applicable
- 24. Incorrect count

### FUNCTIONAL INSPECTION

N/A

### DIMENSIONAL INSPECTION

N/A



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**MAJOR DEFECTS**

***AQL 1.5 is applicable to all defects cumulatively.***

**UNIT**

**VISUAL INSPECTION**

- 25. Dirt / grease / oil
- 26. Ink spots/ smudges
- 27. Embedded foreign matter
- 28. Empty package
- 29. Component in seal
- 30. Miscellaneous Major Defect

**FUNCTIONAL INSPECTION**

N/A

**DIMENSIONAL INSPECTION**

N/A

**DISPENSER**

**VISUAL INSPECTION**

N/A

**FUNCTIONAL INSPECTION**

N/A

**DIMENSIONAL INSPECTION**

N/A

**SHIPPING CONTAINER**

**VISUAL INSPECTION**

N/A





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**FUNCTIONAL INSPECTION**

N/A

**DIMENSIONAL INSPECTION**

N/A

**MINOR DEFECTS**

*AQL 2.5 is applicable to all defects cumulatively.*

**UNIT**

**VISUAL INSPECTION**

- 31. Loose foreign matter
- 32. Discoloration
- 33. Miscellaneous Minor Defect

**FUNCTIONAL INSPECTION**

- 34. Does not pass the barcode verification testing-Refer to SOP 10-13

**DIMENSIONAL INSPECTION**

N/A

**DISPENSER**

**VISUAL INSPECTION**

N/A

**FUNCTIONAL INSPECTION**

N/A

**DIMENSIONAL INSPECTION**

N/A

**SHIPPING CONTAINER**

**VISUAL INSPECTION**

N/A



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**FUNCTIONAL INSPECTION**

N/A

**DIMENSIONAL INSPECTION**

N/A

**REVISION HISTORY**

DATE	DCO#	REASON FOR CHANGE	CHANGE FROM:	CHANGE TO:	REQUESTED BY:
8/12/2015	015756	Creating new QAS for Suture Removal Kits for 4 lanes tooling running on Dixie Vac 3.	N/A	N/A	M. Vera
5/18/2017	017386	Busse is implementing a system to inspect labeling barcode on shipper container, Dispensers, and package units due to UDI regulations, also revise the seal strength test, therefore QAS need to be revised for accuracy.	Current Specification ANSI/ASQC- Z1.4-2008	1-Add Barcode Verification Inspection to Packaging Unit on Minor Defect. 2- Add incorrect tape color-Refer to SOP 09-98- If applicable for shipper carton defects. 3- ANSI/ASQC- Z1.4-2003 (R 2013) 4- Add TM 113 to the seal strength test.	P. Reyes
1/24/2019	019005	Management has decided to inspect dispensers, therefore QAS need to be revised for accuracy.	DISPENSER: (VISUAL): N/A (FUNCTIONAL): N/A (DIMENSIONAL): N/A	DISPENSER: (VISUAL): FOUR DISPENSERS PER INSPECTION-IF APPLICABLE REFER TO THE DHR (FUNCTIONAL): N/A (DIMENSIONAL): N/A	P. Reyes

DOCUMENT APPROVAL – Original Signatures appear on referenced DCO.

Quality Manager  
Packaging Manager  
Quality Lead Inspector  
Quality Technician