



Complaint Number: 101669

Report 8D

Generated By: Christine Hulme
Generated On: 16 Nov 2011

I. COMPLAINT INFORMATION

| | | | |
|------------------------|----------------------|-------------------|--------|
| Origination Date | 20 Oct 2011 | | |
| Sales Name | Mark Jones | Sales Office | Ashton |
| Telephone | 07919005137 | Fax Number | |
| Email | mark.jones@scapa.com | | |
| Customer Complaint Ref | | | |
| Customer Name | Finesse Medical Ltd | | |
| SAP Customer Number | 125449 | Customer Order N° | |
| Customer Part Number | | | |

1) Invoices And Items On Complaint

| | | | |
|--|------------|--------------|-------------|
| (a) SAP Invoice Number | 9100222942 | Invoice Date | 19 Apr 2010 |
| - Material | 150715 | Batch | |
| Material Description M6016/877 slit roll 225mm x 1m | | | |
| (b) SAP Invoice Number | 9100245810 | Invoice Date | 14 Jul 2011 |
| - Material | 150715 | Batch | |
| Material Description M6016/877 slit roll 225mm x 1m | | | |

2) Problem Description

FM625 473700 B081 B083 380mts 1895108 - visible contamination under PU film side of each roll.

FM893 552605 C092 C096 C178 C179 1,000mts 2046141 - 5 rolls have a line running through the material. Line is a straight non-adhered normally running parallel to edge of roll.

Actions Requested From The Customer

3) Containment Actions

II. EVALUATION AND ACTION

Sample/photo Received

No

Date

Process Owner

Christine Hulme

Team Leader

jmangan

Is Complaint Valid?

Yes

Return The Goods

No

Dispose The Goods

Yes

Comments

1) Analysis

The samples supplied show what appear to be dust particles on the adhesive side of the film. Some samples show what is a dry line in the adhesive coating.

Author

John Mangan

Date

15 Nov 2011

2) Root Causes

The contamination could be from a number of sources.
Lines in the adhesive are caused by debris or and obstruction in the coating head. This can be due to adhesive gelling up in the coating head or dust/debris from the carrier being coated entering the coating head.

Author

John Mangan

Date

15 Nov 2011

3) Possible Solutions

Author

Date

4) Implemented Perm Corrective Actions

Since the production of this batch, new cleaning schedules have been introduced and implemented. The standard of cleanliness has been raised and the likely causes of contamination have been reduced.

There is no immediate corrective action for lines in the adhesive, as the root cause is not truely understood and it is not as simple as filters on the adhesive line as there is a number of methods for debris to enter the coating head.

Author

John Mangan

Date

15 Nov 2011

Estimated Date

Implementation Date

Validation Date

5) Corrective Actions Validation

Complaints about contamination are not as common, improvement in cleaing and cleaning schedules is continuing.

Author

John Mangan

Date

15 Nov 2011

6) Preventive Actions

| | | | |
|-----------------|--|---------------------|--|
| | | | |
| Author | | Date | |
| Estimated Date | | Implementation Date | |
| Validation Date | | | |

7) Review Of Documentation

(a) MSR

| | | | |
|-----------|----|------|--|
| Reviewed? | No | | |
| Reference | | Date | |

(b) Flow chart, control plan, work inspection instructions

| | | | |
|-----------|----|------|--|
| Reviewed? | No | | |
| Reference | | Date | |

(c) FMEA

| | | | |
|-----------|----|------|--|
| Reviewed? | No | | |
| Reference | | Date | |

(d) Customer specification

| | | | |
|-----------|----|------|--|
| Reviewed? | No | | |
| Reference | | Date | |

8) Congratulate The Team