

## Report 8D

Generated By: Christine Hulme Generated On: 02 Jun 2011

## I. COMPLAINT INFORMATION

Origination Date	19 May 2011					
Sales Name	Daniel Ephgrave	Sales Office	Dunstable			
Telephone	+44 1582 474 655	Fax Number				
Email	daniel.ephgrave@scapa.com					
Customer Complaint Ref						
Customer Name	Given Imaging Ltd					
SAP Customer Number	116096	Customer Order N°				
Customer Part Number						
1) Invoices And Items	s On Complaint					
(a) SAP Invoice Number	9100242120	Invoice Date	26 Apr 2011			
(4) 6/ 4 11/0/06 (14/1/25)	0100212120	invoice Bate	207101			
- Material	140432	Batch				
	Material Description					
	ASM-0057-01 5 Pk Sleeve					
2) Problem Description						
Foreign material (paper) found which has made a scuff mark on the patient's skin. Why is there paper in that location?						
Actions Requested From The Customer						
Why was there paper in that location						
3) Containment Actio	ons					

## II. EVALUATION AND ACTION

Sample/photo Received	Yes					
Date	19 May 2011					
Process Owner	Christine Hulme					
Team Leader	spearce					
Is Complaint Valid?	Yes Return The Goods		Dispose The Goods			
Comments						
1) Analysis						
·	to us ,it looks like there is a segment of the re	elease paper for the 25350 Clot	h tape self Adh still			
attached to the cloth.						
Author	Simon Pearce	Date	23 May 2011			
2) Root Causes						
This may have been caused if there was trouble i:e(Web break) and the resultant pouch with the paper intact was missed and not removed.						
Author	Simon Pearce	Date	23 May 2011			
3) Possible Solutions						
Author		Date				
4) Implemented Perm Corrective Actions						
The operators are aware that any defective pouches are removed at production source. This will be reiterated to them.						
This is a manual operation and does rely on the observance of the operators at both manufacture and packing .						
Author	Simon Pearce	Date	23 May 2011			
Estimated Date	27 May 2011	Implementation Date	31 May 2011			
Validation Date						
5) Corrective Actions Validation						
Operators to be briefed as to the complaint.						
Author	Simon Pearce	Date	31 May 2011			

## 6) Preventive Actions

Author		Date			
Estimated Date		Implementation Date			
Validation Date					
Validation Date					
7) Review Of Docum	entation				
•					
(a) MSR					
	No				
Reviewed?	No				
Reference		Date			
receive		Bate			
(b) Flow chart, control plan	n, work inspection instructions				
Reviewed?	No				
Reference		Date			
Releielice		Date			
(c) FMEA					
Reviewed?	No				
Reference		Date			
(d) Customer and differentian					
(d) Customer specification					
Reviewed?	No				
Reference		Date			

8) Congratulate The Team