





Report 8D

Generated By: Christine Hulme Generated On: 01 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 On Complaint						
1) IIIVOICES AND ITEM						
(a) SAP Invoice Number	9100242120	Invoice Date	26 Apr 2011			
- Material	140432	Batch				
	Material Description					
	ASM-0057-01 5 Pk Sleeve					
2) Problem Description						
The labels of the item are wrong. The caption states "ASM-0056-01" instead of "ASM-0057-01"						
Actions Requested From The Customer						
corrective actions						
3) Containment Actions						

Customer care asked the customer if we can supply labels with correct information to them for applying.

II. EVALUATION AND ACTION Sample/photo Received No Date Simon Pearce Process Owner Team Leader spearce Is Complaint Valid? Yes Return The Goods Dispose The Goods Comments 1) Analysis From the photographs supplied it seems that labels for the "5 pack of 8 "packs have been used for the "5 spare pockets" Author Simon Pearce 23 May 2011 Date 2) Root Causes When packing these pouches ,the wrong labels were used by the operators.45 packs were labelled up incorrectly. The 5 pack of 8 labels were left over from a previous job. 23 May 2011 Author Simon Pearce Date 3) Possible Solutions Author Date 4) Implemented Perm Corrective Actions Replacement labels were sent to the customer. labels from the previous jobs to be removed from the cleanroom or thrown away before the next packing job is started. Operators to be briefed on this complaint.

Author Simon Pearce 23 May 2011 Date **Estimated Date** 24 May 2011 Implementation Date 24 May 2011 Validation Date

5) Corrective Actions Validation

Author	Date	

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