



Complaint Number: 100263

## Report 8D

Generated By: Christine Hulme  
Generated On: 03 Jun 2011

### I. COMPLAINT INFORMATION

Origination Date	01 Jun 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	Welland Medical Limited		
SAP Customer Number	116117	Customer Order N°	
Customer Part Number			

#### 1) Invoices And Items On Complaint

#### 2) Problem Description

Welland have received a complaint from one of their customers regarding the Supla plasters (PLA 100) where they feel the adhesive on the plaster is not sticky enough & thought the adhesive may be different.

Actions Requested From The Customer

#### 3) Containment Actions

II. EVALUATION AND ACTION

Sample/photo Received

Yes

Date

01 Jun 2011

Process Owner

Paul Rochford

Team Leader

prochford

Is Complaint Valid?

Yes

Return The Goods

No

Dispose The Goods

Yes

Comments

1) Analysis

The adhesive properties of the product were tested on the 19-May-10

Batch Log180 degree Avg -180 degree Max -Peel Fail

B3300 15.296.63TP

B3300 26.4611.95TP

B3300 34.439.59TP

All tests are within specification (Min 5N), except B3300 3 at 4.43.

B3300 3 is the complaint batch.

Author

Paul Rochford

Date

01 Jun 2011

2) Root Causes

The log should have been put on hold.

Author

Paul Rochford

Date

02 Jun 2011

3) Possible Solutions

Author

Date

4) Implemented Perm Corrective Actions

Revised the non-conformance system & labelling.

QC Lab testers aware of this mistake.

Author

Paul Rochford

Date

03 Jun 2011

Estimated Date

Implementation Date

Validation Date

5) Corrective Actions Validation

Ongoing assessment of lab findings & non-conformance reaction.

Author

Paul Rochford

Date

03 Jun 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