



24/May/2013

## Post market Surveillance and Risk Assessment Re-evaluation

Heat Shields
Viamed Product
Post market Surveillance
Risk Assessment
Stock References Review
Supplier Review
Sales Review
Country Sales Review
Stock Returns Review
Design Changes Review
User Manuals Review
Labels Review
Document Updates Review
Internal Issues Review
Clinical Information Review
FDA Incidents Review
Carried out by Derek Lamb on 24 / 05 / 13

## Stock References Reviewed

Stock Reference	Description
PP8100	Heat Shield Open Ends
PP8101	Heat Shield one end open
PP8102	Heat Shield Both Ends Closed
PP8103	Heat Shield Open Ends
PP8104	Heat Shield One End Closed
PP8105	Heat Shield Both Ends Closed
PP8106	Heat Shield Open Ends
PP8107	Heat Shield Open One End
PP8108	Heat Shield Both Ends Closed
PP8109	Heat Shield Open Ends
PP8110	Heat Shield One End Closed
PP8111	Heat Shield Both Ends Closed
PP8112	Heat Shield Open Ends
PP8113	Heat Shield One End Closed
PP8114	Heat Shield Both Ends Closed
PP8601	Heat Shield Open Ends
PP8620	Heat Shield One End Closed
PP8633	Heat Shield
PP8761	Heat Shield Both Ends Open
PP8779	Heat Shield Open Ends

Comments on Stock references review:

Checked part numbers, all present

## Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
PP8109	Heat Shield Open Ends	00009022	Tanda Engineering Ltd	A
PP8112	Heat Shield Open Ends	00009022	Tanda Engineering Ltd	A
PP8633	Heat Shield	00009022	Tanda Engineering Ltd	A
PP8761	Heat Shield Both Ends Open	00009022	Tanda Engineering Ltd	A
PP8779	Heat Shield Open Ends	00009022	Tanda Engineering Ltd	A

Comments on Suppliers:

Tanda is only supplier as these are custom products,

## Sales Information

Stock Reference	Description	2007	2008	2009	2010	2011	2012	2013
PP8100	Heat Shield Open Ends							
PP8101	Heat Shield one end open							
PP8102	Heat Shield Both Ends Closed							
PP8103	Heat Shield Open Ends							
PP8104	Heat Shield One End Closed							
PP8105	Heat Shield Both Ends Closed							
PP8106	Heat Shield Open Ends							
PP8107	Heat Shield Open One End							
PP8108	Heat Shield Both Ends Closed							
PP8109	Heat Shield Open Ends	2						
PP8110	Heat Shield One End Closed							
PP8111	Heat Shield Both Ends Closed							
PP8112	Heat Shield Open Ends	5	-4					
PP8113	Heat Shield One End Closed							
PP8114	Heat Shield Both Ends Closed							
PP8601	Heat Shield Open Ends							
PP8620	Heat Shield One End Closed							
PP8633	Heat Shield	2						
PP8761	Heat Shield Both Ends Open		8	2			7	2
PP8779	Heat Shield Open Ends						2	

Comments on Sales Information:

units sell, albiet in very limited numbers

## New Countries

Country	2007	2008	2009	2010	2011	2012	2013
UK United Kingdom	[X]	[X]	[X]			[X]	[X]

Comments on Sales to Countries:

Have only ever sold to the UK

Comments on Risks with Sales to Countries:

no applicable

## Returns Information

Comments on Returns:

zero returns

Comments on Risks with Returns and Potential Re-work:

not applicable

## Design Changes / Product Changes

### Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no changes to product files

Comments on Risks with Design Changes:

not applicable

## User Instructions

### Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
7688	Heat Shields Instructions for Use User Manual	15/02/11

Comments on User Instructions:

no changes to user instructions

Comments on Risks User Instructions:

not applicable



## Labels

### Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
9169	No accessory labels	18/10/11
7498	Head Box Oxygen Hoods Labels	21/01/11

Comments on Labels:

Comments on Risks Labels:

not applicable

# Documentation Updates / Changes

Comments on Document Changes:

added some documents such as expected life of the product to keep standards upto date,  
nothing of ant real significance added

Comments on Risks with Document Changes:

not applicable

## Review of Issues

Number of Issues reviewed: 0

Comments on Issues:

no Issues found with regard to heat shields

Comments on Risks with Issues:

not applicable

## Review of online clinical reports

Do any of the Results indicate a Risk / Problem : No

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

very little found on the web.

## Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem : No

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

no FDA reports were found