



21/Mar/2012

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 21 / 03 / 12

Stock References Reviewed

Stock Reference	Description
PP8100	Heat Shield Open Ends
PP8101	Heat Shield one end open
PP8102	Heat Shield Both Ends Open
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 Both Ends Closed
PP8633	Heat Shield
PP8761	Heat Shield Both Ends Open

Comments on Stock references review:

no new numbers have been added

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

Comments on Suppliers:

Supplier is still current, as is supplier rating,

Sales Information

Stock Reference	Description	2006	2007	2008	2009	2010	2011	2012
PP8100	Heat Shield Open Ends							
PP8101	Heat Shield one end open							
PP8102	Heat Shield Both Ends Open							
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 Both Ends Closed							
PP8633	Heat Shield		2					
PP8761	Heat Shield Both Ends Open			8	2			

Comments on Sales Information:

had Zero sales of Heat Shields for 2 Years,Add follow up to see if we contiune with the product or reduce the stock holding.

Follow up Issue #35221

New Countries

Country	2006	2007	2008	2009	2010	2011	2012
UK United Kingdom		[X]	[X]	[X]			

Comments on Sales to Countries:

Only sold to U.K.

Comments on Risks with Sales to Countries:

No new countries

Returns Information

Comments on Returns:

not a product that gets returns due to the nature.

Comments on Risks with Returns and Potential Re-work:

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

Document is updated PDF not a new new document,

Comments on Risks with Design Changes:

No design changes have occurred

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:

Document is updated PDF not a new new document, No instructions of use are required for this product.

Comments on Risks User Instructions:

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:

No risks associated with labels

Documentation Updates / Changes

Comments on Document Changes:

Lots of old files have been updated to PDF's
and a few product life type documents added,

Comments on Risks with Document Changes:

No risks associated with new documentation

Review of Issues

Number of Issues reviewed: 0

Comments on Issues:

No Issues found in the system

Comments on Risks with Issues:

No Issues found in the system

Review of online clinical reports

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

Do any of the Results indicate outdated Technology : Yes

Comments on Clinical Search :

35222

Risk Search No

Out of Date Search Yes

Radiant warmers versus incubators for regulating body temperature in newborn infants
has brought up possible outcomes, requires further reading. may indicate why sales have stopped.

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 found