



24/May/2013

Post market Surveillance and Risk Assessment Re-evaluation

Light 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
PP8400	Phototherapy Light Shield - Size 1.
PP8509	Phototherapy Light Shield/Oxygen Hood.
PP8510	Phototherapy Light Shield - Size 1.
PP8533	Phototherapy Light Shield/Oxygen Hood.
PP8540	Phototherapy Light Shield/Oxygen Hood.
PP8559	Phototherapy Light Shield - Size 2.
PP8560	Phototherapy Light Shield - Size 2.
PP8562	Phototherapy Light Shield/Oxygen Hood.
PP8563	Phototherapy Light Shield - Size 3.
PP8565	Phototherapy Light Shield/Oxygen Hood.
PP8689	Phototherapy Light Shield - Size 1b.

Comments on Stock references review:

confirmed stock references are correct

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
PP8400	Phototherapy Light Shield - Size 1.	00009022	Tanda Engineering Ltd	A
PP8509	Phototherapy Light Shield/Oxygen Hood.	00009022	Tanda Engineering Ltd	A
PP8510	Phototherapy Light Shield - Size 1.	00009022	Tanda Engineering Ltd	A
PP8533	Phototherapy Light Shield/Oxygen Hood.	00009022	Tanda Engineering Ltd	A
PP8559	Phototherapy Light Shield - Size 2.	00009022	Tanda Engineering Ltd	A
PP8560	Phototherapy Light Shield - Size 2.	00009022	Tanda Engineering Ltd	A
PP8562	Phototherapy Light Shield/Oxygen Hood.	00009022	Tanda Engineering Ltd	A
PP8689	Phototherapy Light Shield - Size 1b.	00009022	Tanda Engineering Ltd	A

Comments on Suppliers:

Tanda is the only supplier of light shields,

Sales Information

Stock Reference	Description	2007	2008	2009	2010	2011	2012	2013
PP8400	Phototherapy Light Shield - Size 1.	17	33	16	7	2	5	18
PP8509	Phototherapy Light Shield/Oxygen Hood.	8		2	9	1		1
PP8510	Phototherapy Light Shield - Size 1.	7	11	5	1	1	6	2
PP8533	Phototherapy Light Shield/Oxygen Hood.	4		2	1	0		
PP8540	Phototherapy Light Shield/Oxygen Hood.							
PP8559	Phototherapy Light Shield - Size 2.	8	8		1		5	
PP8560	Phototherapy Light Shield - Size 2.		1		2	0	1	
PP8562	Phototherapy Light Shield/Oxygen Hood.	4					1	
PP8563	Phototherapy Light Shield - Size 3.						1	
PP8565	Phototherapy Light Shield/Oxygen Hood.							
PP8689	Phototherapy Light Shield - Size 1b.		5					

Comments on Sales Information:

units selling,

New Countries

Country	2007	2008	2009	2010	2011	2012	2013
BA State of Bahrain						[X]	
CHA Channel Islands							
GR Greece	[X]			[X]			
IN India							[X]
JO Jordan							
MA Malaysia							
NE Netherlands							
OM Oman		[X]	[X]				[X]
SWI Switzerland		[X]					
UAE U.A.E.	[X]						
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

New countries India and State of Bahrain,

Comments on Risks with Sales to Countries:

No risks identified with the new countries

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 document changes in the design 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
1990	Light Shields Instructions for use Light Shields User Manual	18/06/07

Comments on User Instructions:

no changes to the user manual

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
8192	Light Shields Labels	30/03/11
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:

some documents from the old paper system have been scanned in,
no actual changes to the product have occurred,
and some extra files such as expected life have been added to comply with recent regulations

Comments on Risks with Document Changes:

not applicable

Review of Issues

Number of Issues reviewed: 1

Issue ID	Subject
30332	Returned Items SOR478

Comments on Issues:

Only issue on system is a process/selling Issue

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 :

difficult subject to search due to nature of the wording, however nothing found to say the technology is outdated.
although eye masks seem more popular.

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 that were relevant