



21/Mar/2012

## 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 21 / 03 / 12

## 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:

No new stock items have been added,

## 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
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:

Supplier information is uptodate and correct.

## Sales Information

Stock Reference	Description	2006	2007	2008	2009	2010	2011	2012
PP8400	Phototherapy Light Shield - Size 1.	12	17	33	16	7	2	
PP8509	Phototherapy Light Shield/Oxygen Hood.		8		2	9	1	
PP8510	Phototherapy Light Shield - Size 1.	7	7	11	5	1	1	3
PP8533	Phototherapy Light Shield/Oxygen Hood.	4	4		2	1	0	
PP8540	Phototherapy Light Shield/Oxygen Hood.							
PP8559	Phototherapy Light Shield - Size 2.	4	8	8		1		
PP8560	Phototherapy Light Shield - Size 2.	1		1		2	0	
PP8562	Phototherapy Light Shield/Oxygen Hood.	2	4					
PP8563	Phototherapy Light Shield - Size 3.							
PP8565	Phototherapy Light Shield/Oxygen Hood.							
PP8689	Phototherapy Light Shield - Size 1b.	6		5				

Comments on Sales Information:

Units are selling albiet in small numbers.

## New Countries

Country	2006	2007	2008	2009	2010	2011	2012
CHA Channel Islands							
GR Greece		[X]			[X]		
JO Jordan	[X]						
MA Malaysia							
NE Netherlands							
OM Oman			[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:

no new countries have been added in the last couple of years

Comments on Risks with Sales to Countries:

no risk identified with countries

# Returns Information

Comments on Returns:

Product has no returns.

Comments on Risks with Returns and Potential Re-work:

Product has no returns / no reworks

## Design Changes / Product Changes

### Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

updated document is a PDF version of an old document,

Comments on Risks with Design Changes:

no Risks identified.

## User Instructions

### Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
8191	Light Shields Instructions for Use User Manual	30/03/11
1990	Light Shields Instructions for use	18/06/07

Comments on User Instructions:

do a document search in intrastats for Light Shields Instructions we appear to have 2 live versions, pretty sure which is current but will double check with Steve Nixon  
Follow up Issue #35223

Comments on Risks User Instructions:

No risks with instructions



## 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:

no risks with labels

# Documentation Updates / Changes

Comments on Document Changes:

brought some sections upto date stating no latex / animal prducts etc..

Comments on Risks with Document Changes:

no risks identified with products

## Review of Issues

Number of Issues reviewed: 5

Issue ID	Subject
30332	Returned Items SOR478
28434	Eden Medical
28433	Eden Medical
29716	POR07931 PP8509 Delivery date Change
29715	POR07931 PP8509 Delivery date Change

Comments on Issues:

only 4 Issues relevant, to do with stock and back orders

Comments on Risks with Issues:

no risks found with issues

## 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 :

No risks identified, or indications use is out of date,

however, noted that light shield is a fairly vagues search and difficult to bring much up out of google with any relevance

## 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 identified, or indications use is out of date,

however, noted that light shield is a fairly vagues search and difficult to bring much up out of google with any relevance