



VIA MED

Phototherapy Light Shields












Amber perspex head cover enabling phototherapy to be administered whilst the eyes are protected.

Class I
Via Rule Rule 9
Assesment Route Annex II
NBOG MD 0100

Carried out by Derek Lamb
18 / 11 / 19



VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
-  Countries Review
-  Returns Review
-  Design Changes Review
-  User Instructions Review
-  Labels Review
-  Document Updates Review
-  Internal Issues Review
-  Clinical / FDA Incidents online search

Stock References Review

Stock Reference	Description
PP8400	Phototherapy Light Shield - Size 1.
PP8510	Phototherapy Light Shield - Size 1.
PP8559	Phototherapy Light Shield - Size 2.
PP8560	Phototherapy Light Shield - Size 2.
PP8563	Phototherapy Light Shield - Size 3.
PP8689	Phototherapy Light Shield - Size 1b.

Comments on Stock references review:

part number upto date

- No longer Selling / producing these products

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
PP8400	Phototherapy Light Shiel	00009022	PP8400	Tanda Engineering Ltd	B
PP8510	Phototherapy Light Shiel	00009022	PP8510	Tanda Engineering Ltd	B
PP8559	Phototherapy Light Shiel	00009022	PP8559	Tanda Engineering Ltd	B
PP8560	Phototherapy Light Shiel	00009022	PP8560	Tanda Engineering Ltd	B
PP8563	Phototherapy Light Shiel	00009022	PP8563	Tanda Engineering Ltd	B
PP8689	Phototherapy Light Shiel	00009022	PP8689	Tanda Engineering Ltd	B

Comments on Suppliers:

No longer Selling / producing these products

Sales Information

Stock Reference	Description	2013	2014	2015	2016	2017	2018	2019
PP8400	Phototherapy Light Shiel	24	0	10	2		2	
PP8510	Phototherapy Light Shiel	8	2	5	1			
PP8559	Phototherapy Light Shiel	1	0					
PP8560	Phototherapy Light Shiel				1			1
PP8563	Phototherapy Light Shiel				1	-1		
PP8689	Phototherapy Light Shiel	3			1			

Comments on Sales Information:

No longer Selling / producing these products

Countries Review

Country	2013	2014	2015	2016	2017	2018	2019
ARM ARMENIA						[X]	
BA Kingdom of Bahrain							
CHA Channel Islands							
GR Greece							
MA Malaysia							
NE Netherlands							
NI Northern Ireland							
OM Oman	[X]						
SC Scotland			[X]				
SP Spain				[X]	[X]		
SWI Switzerland							
UAE U A E							
UK United Kingdom	[X]	[X]	[X]	[X]			[X]

Comments on Sales to Countries:

No longer Selling / producing these products

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2013	2014	2015	2016	2017	2018	2019
PP8560	Unchecked - Returned To Stock							
PP8563	No Fault Return To Stock					1		

Comments on Returns:

no returns

Comments on Risks with Returns and Potential Re-work:

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no product changes

Comments on Risks with Design Changes:

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
14780	Light Shields Instructions for use Light Shields User Manual 049...	19/02/15

Comments on User Instructions:

no product changes

Comments on Risks User Instructions:

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
16792	Head Box Oxygen Hoods Labels	20/04/16
9169	No accessory labels	18/10/11
8192	Light Shields Labels	30/03/11

Comments on Labels:

no product changes

Comments on Risks Labels:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
29753	Viamed CE Certificate CE01389 Internal Use Only Cancellation Le...	29/05/19

Comments on Document Changes:

no product changes

Comments on Risks with Document Changes:

Internal Issues Review

Number of Issues reviewed: 1

Issue ID	Subject
135910	Xero Accounts Upgrade Sales Back Orders Review - By Customer Backorder 00003500 PP8560 ORD96057

Comments on Issues:

no issues

Comments on Risks with Issues:

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003500 PP8560 ORD96057

Issue ID #135910

Date Created 10/Jan/2019

Issued To: General

Completed Status: 15 Jan 2019

Stock Ref: PP8560

Opera A/c: 00003500

Order Number: ORD96057

Notes:

10 Jan 2019 03:41:11 PM Zoey Teal

See Attached Notes

Advised a £10.00 carriage for this order and also advised that we only have 1 of part number PP8560 in stock and the rest are discontinued.

Issues:135910

Clinical / FDA Incidents online search

Clinical Investigation online review

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

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

no product changes

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 product changes