



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 / 01 / 21



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:

No product changes
all products discontinued

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 product changes
all products discontinued
no supplier review required

Sales Information

Stock Reference	Description	2015	2016	2017	2018	2019	2020	2021
PP8400	Phototherapy Light Shiel	10	2		2			
PP8510	Phototherapy Light Shiel	5	1					
PP8559	Phototherapy Light Shiel							
PP8560	Phototherapy Light Shiel		1			1	1	
PP8563	Phototherapy Light Shiel		1	-1				
PP8689	Phototherapy Light Shiel		1					

Comments on Sales Information:

No product changes

all products discontinued

ebay sales to non medical customers (gardening)

Countries Review

Country	2015	2016	2017	2018	2019	2020	2021
Armenia				[X]			
BA State of Bahrain							
Greece							
Guernsey							
Northern Ireland	[X]	[X]					
Oman							
Scotland							
Spain		[X]	[X]				
SWI Switzerland							
UK	[X]				[X]		
UK United Kingdom		[X]					
Zambia						[X]	

Comments on Sales to Countries:

No product changes
all products discontinued

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2015	2016	2017	2018	2019	2020	2021
PP8560	Unchecked - Returned To Stock							
PP8563	No Fault Return To Stock			1				

Comments on Returns:

No product changes
all products discontinued

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
all products discontinued

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
all products discontinued

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
all products discontinued

Comments on Risks Labels:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
31688	Light Shields Clinical Trials Reports Reviews and Post Market Su...	18/11/19

Comments on Document Changes:

No product changes
all products discontinued

Comments on Risks with Document Changes:

Internal Issues Review

Number of Issues reviewed: 1

	Subject
	PP8400 Phototherapy Light Shield, Size 1 165 mm (L) x 215 mm (W) x 150 mm (H) (Internal) For use with PP8000 oxygen h
	<p>Comments on Issues:</p> <p>No product changes all products discontinued</p> <p>Comments on Risks with Issues:</p>

VIAMED Stock Meeting - Stock Queries

**PP8400 Phototherapy Light Shield, Size 1
165 mm (L) x 215 mm (W) x 150 mm (H) (I**

Issue ID #204464

Date Created 11/Nov/2020

Issued To: Derek Lamb

Completed Status: 13 Nov 2020

Notes:

Added by Catrin Hird sent to Derek Lamb

I believe this bar code needs to be killed as it could not be found.

12 Nov 2020 Derek Lamb
done

13 Nov 2020 Catrin Hird
Thanks

Issues:204464

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
all products discontinued

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
all products discontinued