



VIA MED

Phototherapy Light Shields

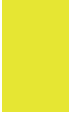

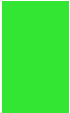








Amber perspex head cover enabling phototherapy to be administered whilst the eyes are protected.

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

Carried out by Derek Lamb
02 / 02 / 22



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:

only sold old stock to non ce marked countries 2015
suggest remove from PMS cycle

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:

only sold old stock to non ce marked countries 2015
suggest remove from PMS cycle

Sales Information

Stock Reference	Description	2016	2017	2018	2019	2020	2021	2022
PP8400	Phototherapy Light Shiel	2		2				
PP8510	Phototherapy Light Shiel	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:

only sold old stock to non ce marked countries 2015
suggest remove from PMS cycle

Countries Review

Country	2016	2017	2018	2019	2020	2021	2022
Armenia			[X]				
BA State of Bahrain							
Greece							
Guernsey							
Northern Ireland	[X]						
Oman							
Scotland							
Spain	[X]	[X]					
Switzerland							
UK				[X]			
UK United Kingdom	[X]						
Zambia					[X]		

Comments on Sales to Countries:

only sold old stock to non ce marked countries 2015
suggest remove from PMS cycle

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2016	2017	2018	2019	2020	2021	2022
PP8560	Unchecked - Returned To Stock							
PP8563	No Fault Return To Stock		1					

Comments on Returns:

only sold old stock to non ce marked countries 2015
suggest remove from PMS cycle

Comments on Risks with Returns and Potential Re-work:

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

only sold old stock to non ce marked countries 2015
suggest remove from PMS cycle

Comments on Risks with Design Changes:

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
75073	Light Shields Instructions for use Light Shields User Manual 049...	16/11/21

Comments on User Instructions:

only sold old stock to non ce marked countries 2015
suggest remove from PMS cycle

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:

only sold old stock to non ce marked countries 2015
suggest remove from PMS cycle

Comments on Risks Labels:

Documentation Updates / Changes

Comments on Document Changes:

only sold old stock to non ce marked countries 2015
suggest remove from PMS cycle

Comments on Risks with Document Changes:

Clinical / FDA Incidents online search

Clinical Investigation online review

Comments on Issues:

no issues

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

Do any of the Results indicate outdated Technology : No

Comments on Clinical Search :

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 :