



# 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 / 08 / 16



# 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
-  Risk ISO 14971 : 2012 Review

# 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:

stock references upto date,  
removed the oxyegn hood versions and added to the oxygen Hood File.

After discussions with BSI Technical manager. it has been determined the phototherapy component, and simple light shields are not class II devices.

See email history with a Vishal Thakker. doc id 17289

# Supplier Review

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

Comments on Suppliers:

supplier reviews up to date

# Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
PP8400	Phototherapy Light Shiel	10	2	5	24	0	10	2
PP8510	Phototherapy Light Shiel	2	1	6	8	2	5	1
PP8559	Phototherapy Light Shiel	1		5	1	0		
PP8560	Phototherapy Light Shiel	4	-1	1				1
PP8563	Phototherapy Light Shiel			1				
PP8689	Phototherapy Light Shiel				3			

Comments on Sales Information:

units still selling but in limited numbers

# Countries Review

Country	2010	2011	2012	2013	2014	2015	2016
BA State of Bahrain			[X]				
CHA Channel Islands							
GR Greece	[X]						
MA Malaysia							
NE Netherlands							
OM Oman				[X]			
SWI Switzerland							
UAE U A E							
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

only sold to the uk in the last few years

Comments on Risks with Sales to Countries:

n/a

# Returns Review

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
PP8560	Unchecked - Returned to Stock							

Comments on Returns:

no returns

Comments on Risks with Returns and Potential Re-work:

n/a

# Design Changes Review

## Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no design changes

but some products removed from this file into the oxygen hood file.

removed the oxygen hood versions and added to the oxygen Hood File.

After discussions with BSI Technical manager. it has been determined the photo therapy component, and simple light shields are not class II devices.

See email history with a Vishal Thakker.

Comments on Risks with Design Changes:

n/a



# 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 changes to the user instructions

Comments on Risks User Instructions:

n/a

# 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:

Shipping handel with care label added to the outer packaging

Comments on Risks Labels:

n/a

# Documentation Updates / Changes

Document ID	Description	Date Added/Updated
17289	Phototherapy Light Shields Notified Body Reports should be class...	18/08/16
16792	Head Box Oxygen Hoods Labels	20/04/16
16715	Phototherapy Light Shields Quality Assurance and Agreements else...	05/04/16
15998	Promotional Leaflets Phototherapy Light Shield and Hoods (High)	18/11/15
15669	Oxygen Hoods and Phototherapy Leaflet (email)	18/09/15
15617	Heat Shields Packaging Trials and validation 2015 Returned	09/09/15
15616	Heat Shields Packaging Trials and validation 2015 Shipping Out	09/09/15
15615	Heat Shields Packaging Trials and validation 2015 Packaging	09/09/15
15614	Heat Shields Packaging Trials and validation 2015	09/09/15
15427	Phototherapy Light Shields Risk analysis reports	11/08/15
15418	PPE Equipment	11/08/15
15297	Light Shields EC Declaration of Conformanc	29/07/15
15183	No risks disposal	21/07/15
15112	Light Shields Clinical Trials Reports Reviews and Post Market Su...	24/06/15

## Comments on Document Changes:

removed the oxygen hood versions and added to the oxygen Hood File.

After discussions with BSI Technical manager. it has been determined the photo therapy component, and simple light shields are not class II devices.

See email history with a Vishal Thakker.

## Comments on Risks with Document Changes:

n/a

# Internal Issues Review

Number of Issues reviewed: 10

Issue ID	Subject
60858	Backorder 00000200 PP8510 ORD75143
75151	Backorder 00000454 PP8560 ORD81360
76624	Backorder 00000454 PP8689 ORD81360
62098	Backorder 00001291 PP8400 ORD75736
63943	Backorder 00001291 PP8400 ORD76663
76980	Backorder 00001291 PP8400 ORD81843
63456	Backorder 00004080 PP8400 ORD76385
62409	BSI Ref: 1225836N2
76003	POR10875 PP8560 //
76004	POR10875 PP8689 //

Comments on Issues:

no problems found in the Issue system,

Comments on Risks with Issues:

no risks identified in the issue system

# 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 :

only finding articles on dental light curing - not relevant to our light shields.

## 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 found on photo therapy light shields