

NeoMask Phototherapy Eye Occlus

Light occluder which is for use with phototherapy light

Class I
Via Rule Rule 1 includes Eye occ
Assesment Route Annex VII

Carried out by Derek Lamb 16 / 07 / 19



- 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		
1114015	NeoMask Phototherapy Eye Masks - Large		
1114016	NeoMask Phototherapy Eye Masks - Medium		
1114017	NeoMask Phototherapy Eye Masks - Small		
1114020	Phototherapy Masks Type B - Large		
1114021	Phototherapy Masks Type B - Medium		
1114022	Phototherapy Masks Type B - Small		
1114025	Phototherapy Masks Type C - Large		
1114026	Phototherapy Masks Type C - Medium		
1114027	Phototherapy Masks Type C - Small		
1114030	Phototherapy Masks Type D - Large		
1114031	Phototherapy Masks Type D - Medium		
1114032	Phototherapy Masks Type D - Small		
1134014	NeoMask Sample Pack		
1134015	NeoMask Phothotherapy Eye Mask - Large		
1134016	NeoMask Phototherapy Eye - Medium		
1134017	NeoMask Phototherapy Eye Mask - Small		

Comments on Stock references review:

part numbers up to date

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
1114015	NeoMask Phototherapy Eye	00009080	MODEL III	Sunnycare Medical Supply	В
1114016	NeoMask Phototherapy Eye	00009080	MODEL III	Sunnycare Medical Supply	В
1114017	NeoMask Phototherapy Eye	00009080	MODEL III	Sunnycare Medical Supply	В

Comments on Suppliers:

happy with supplier

Sales Information

Stock Reference	Description	2013	2014	2015	2016	2017	2018	2019
1114015	NeoMask Phototherapy Eye	18	132	201	43	113	181	202
1114016	NeoMask Phototherapy Eye	26	267	289	37	125	175	154
1114017	NeoMask Phototherapy Eye	26	99	163	19	135	85	27
1114020	Phototherapy Masks Type B - Large							
1114021	Phototherapy Masks Type B - Medium							
1114022	Phototherapy Masks Type B - Small							
1114025	Phototherapy Masks Type C - Large							
1114026	Phototherapy Masks Type C - Medium							
1114027	Phototherapy Masks Type C - Small							
1114030	Phototherapy Masks Type D - Large							
1114031	Phototherapy Masks Type D - Medium							
1114032	Phototherapy Masks Type D - Small							
1134014	NeoMask Sample Pack	30	25	67	5	6		
1134015	NeoMask Phothotherapy Eye Mask - Large		11					3
1134016	NeoMask Phototherapy Eye - Medium		2					8
1134017	NeoMask Phototherapy Eye Mask - Small							3

Comments on Sales Information:

units are selling in limited numbers

Countries Review

0	0040	0044	0045	0040	0047	0040	0040
Country	2013	2014	2015	2016	2017	2018	2019
AL Algeria		[X]	[X]		[X]		
B Belgium	[X]	[X]	[X]			[X]	
BU Bulgaria		[X]				[X]	
CY Cyprus	[X]	[X]				[X]	[X]
DE Denmark					[X]		
F France	[X]						
GR Greece		[X]				[X]	[X]
HK Hong Kong				[X]			
HU Hungary	[X]	[X]	[X]		[X]	[X]	[X]
IN India	[X]			[X]			
IND Indonesia							[X]
IT Italy			[X]	[X]	[X]	[X]	
JO Jordan		[X]					
KE Kenya	[X]						
KU Kuwait		[X]					
LI Lithuania		[X]		[X]		[X]	[X]
ML Malta			[X]				
NE Netherlands			[X]			[X]	[X]
NI Northern Ireland							[X]
OM Oman		[X]					
P Poland	[X]	[X]					
PAL Palestine						[X]	
PO Portugal						[X]	[X]
RO Romania	[X]			[X]	[X]		
SC Scotland		[X]					
SER Serbia					[X]	[X]	[X]
SP Spain		[X]	[X]	[X]	[X]	[X]	[X]
SWI Switzerland	[X]						
UAE U A E		[X]	[X]				
UK United Kingdom			[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

selling to multiple countries, albeit in limited numbers

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

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 design changes

Comments on Risks with Design Changes:

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
14935	Instructions for Use User Manual printing label	15/04/15

Comments on User Instructions:

no changes to instructions

Comments on Risks User Instructions:

Labels Review

Showing Documents Filed in F7/F8 Labels

Document ID	Description	Date Added/Updated
13084	PROJECT_29 Phototherapy Masks (sunny) Labels Sunny packing labe	15/10/13
13068	Packaging NeoMask Phototherapy Eye Masks - Small (2487 / 1846) 1	15/10/13
12962	PROJECT_29 Phototherapy Masks (sunny) Labels Packaging Labels	11/09/13
12919	PROJECT_29 Phototherapy Masks (sunny) OES (OEM) Instructions for	21/08/13

Comments on Labels:

no label changes

Comments on Risks Labels:

no risks with labels

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
26612	NeoMask Phototherapy Eye Occlusion Shields Notified body certifi	29/06/18
26610	PROJECT_29 Phototherapy Masks (sunny) Certification ISO 13485:20	29/06/18
26429	NeoMask Phototherapy Eye Occlusion Shields Clinical Trials Repor	13/06/18

Comments on Document Changes:

certificates updated

Comments on Risks with Document Changes:

Internal Issues Review Number of Issues reviewed: 27

Issue ID	Subject
143155	Office Meeting Audit Goods Inwards and Product Identity Audit 09 Goods Inward And Product Identity Viamed (170)
139994	Office Meeting Audit Goods Inwards and Product Identity Audit 09 Goods Inward And Product Identity Viamed (170)
134063	Office Meeting Sales Back Orders Review - By Customer Backorder 00000980 1114015 ORD95629
136075	Office Meeting Sales Back Orders Review - By Customer Backorder 00000980 1114015 ORD96016
129012	Office Meeting Sales Back Orders Review - By Customer Backorder 00000980 1114017 ORD94280
132804	Office Meeting Sales Back Orders Review - By Customer Backorder 00006022 1114015 ORD95178
133267	Office Meeting Sales Back Orders Review - By Customer Backorder 00006022 1114015 ORD95418
134180	Office Meeting Sales Back Orders Review - By Customer Backorder 00006022 1114015 ORD95603
135690	Office Meeting Sales Back Orders Review - By Customer Backorder 00006022 1114015 ORD95969
124481	Office Meeting Sales Back Orders Review - By Customer Backorder 00006251 1114015 ORD93213
132807	Office Meeting Sales Back Orders Review - By Customer Backorder 00006458 1114015 ORD95257
135908	Office Meeting Sales Back Orders Review - By Customer Backorder 00006533 0110040 ORD96030
140087	Office Meeting Sales Back Orders Review - By Customer Backorder 00006673 1114016 ORD96735
135089	Office Meeting Sales Back Orders Review - By Customer Backorder 00007392 1114015 ORD95873
144715	Office Meeting Sales Back Orders Review - By Customer Backorder 00007392 1114015 ORD98028
124593	Office Meeting Sales Back Orders Review - By Customer Backorder 00007518 1114015 ORD93253
130540	Office Meeting Sales Back Orders Review - By Customer Backorder 00007518 1114015 ORD94645
127516	Office Meeting Sales Back Orders Review - By Customer Backorder 00007628 1114015 ORD93964
144095	Office Meeting Sales Back Orders Review - By Customer Backorder 00007628 1114015 ORD97941
140660	Office Meeting Sales Back Orders Review - By Customer Backorder 00007628 1114017 ORD97223
120413	Office Meeting Sales Back Orders Review - By Customer Backorder 00007736 1114015 ORD92214
138257	Office Meeting Sales Back Orders Review - By Customer Backorder 00007736 1114015 ORD96676
144485	Office Meeting Sales Back Orders Review - By Customer Backorder 00007736 1114015 ORD97983
119796	Office Meeting Other Neomask CE certificate 2018-05-07

Issue ID	Subject
134599	Office Meeting Stock Processing Neomask stock count
147518	Office Meeting Sale or Returns Request Scanning Item to Sale or return
125144	Office Meeting Sale or Returns Request Scanning Item to Sale or return SOR868

Comments on Issues:

nothing found of concern in the issue system

Comments on Risks with Issues:

Audits Calander - Audit Goods Inwards and Product Identity

Audit 09 Goods Inward And Product Identity Viamed (170)

Issue ID #143155

Date Created 23/Apr/2019 Issued To: Robert Connor Completed Status: 24 Apr 2019

Notes:

Added by Helen Lamb sent to Robert Connor

Can you have a look at the location of 1114017 NeoMask - Small. Pk 20.

found on shelf 837850 Stock Room 15 Main Office Block 2, Row 3, Shelf 3.

intrastats says on 837857 Stock Room 15 Main Office Block 2, Row 1, Shelf 3

24 Apr 2019 Robert Connor

837857 is the correct main box for booking in stock, but there will be some located on 837850 as that is the quick picking location for neomasks. There is one container for each size on the shelf for easy access for Cathy.

24 Apr 2019 Helen Lamb

Audits Calander - Audit Goods Inwards and Product Identity

Audit 09 Goods Inward And Product Identity Viamed (170)

Issue ID #139994

Date Created 11/Mar/2019 Issued To: Derek Lamb

Completed Status: 03 May 2019

Notes:

System Generated Audit 09 Due

Review Last years Audit see if its still suitable

Before Proceeding you need to update the Processes attached to the Audit

Search the Document in the Index,

View the Admin Page

Copy and Paste the Attached Processes, replacing them in the current audit

Any non Conformances from the Audit: Create a follow up / related Issue, With a time for Completion Immediate Action Plan

Corrective Action Plan

Corrective Action

Confirmation of Resolution

if its a major / critical non conformance complete form QC 18

15 Mar 2019 Helen Lamb

Priority Changed From 5 To 2

23 Apr 2019 Helen Lamb

23 Apr 2019 Helen Lamb

Created Related Issue #143155

Added by Helen Lamb sent to Robert Connor

Can you have a look at the location of 1114017 NeoMask - Small. Pk 20.

found on shelf 837850 Stock Room 15 Main Office Block 2, Row 3, Shelf 3.

intrastats says on 837857 Stock Room 15 Main Office Block 2, Row 1, Shelf 3

23 Apr 2019 Helen Lamb

Created Related Issue #143157

Added by Helen Lamb sent to Derek Lamb

question 15 says Check meeting in Intrastats is completed monthly by MD. But does not specify what the meeting heading is. So i am unsure which meeting I am checking

24 Apr 2019 Helen Lamb

Next Action Changed From Helen Lamb To Derek Lamb completed and attached

24 Apr 2019 Derek Lamb

Backorder 00000980 1114015 ORD95629

Issue ID #134063

Date Created 11/Dec/2018

Issued To: General

Completed Status: 17 Jan 2019

Stock Ref: 1114015 Opera A/c: 00000980

Order Number: ORD95629

Notes:

11 Dec 2018 05:03:00 PM Sarah Walton See Attached Notes Aware of the lead time

13 Dec 2018 08:26:44 AM Catherine Spence Back Order - Supplier

19 Dec 2018 02:24:03 PM Sarah Walton Customer aware of the lead time

10.1000

Backorder 00000980 1114015 ORD96016

Issue ID #136075

Date Created 14/Jan/2019

Issued To: General

Completed Status: 17 Jan 2019

Stock Ref: 1114015 Opera A/c: 00000980 Order Number: ORD96016

Notes:

14 Jan 2019 09:00:45 AM Catherine Spence Back Order - Supplier

L. . . 400075

Backorder 00000980 1114017 ORD94280

Issue ID #129012

Date Created 27/Sep/2018

Issued To: General

Completed Status: 27 Sep 2018

Stock Ref: 1114017 Opera A/c: 00000980

Order Number: ORD94280

Notes:

27 Sep 2018 07:36:36 AM Catherine Spence Shipping Thu 27 Sep 2018

1 100010

Backorder 00006022 1114015 ORD95178

Issue ID #132804

Date Created 23/Nov/2018

Issued To: General

Completed Status: 17 Jan 2019

Stock Ref: 1114015 Opera A/c: 00006022

Order Number: ORD95178

Notes:

23 Nov 2018 08:49:55 AM Catherine Spence Back Order - Supplier

23 Nov 2018 01:13:54 PM Sarah Walton

See Attached Notes

Customer aware of no stock. Need to provide a lead time. Waiting for SN to confirm whether or not we are ordering more.

30 Nov 2018 08:21:55 AM Catherine Spence Back Order - Supplier

12 Dec 2018 02:17:21 PM Kate Griffiths See Attached Notes

13 Dec 2018 08:25:29 AM Catherine Spence Back Order - Supplier

Backorder 00006022 1114015 ORD95418

Issue ID #133267

Date Created 30/Nov/2018

Issued To: General

Completed Status: 17 Jan 2019

Stock Ref: 1114015 Opera A/c: 00006022

Order Number: ORD95418

Notes:

30 Nov 2018 08:22:15 AM Catherine Spence Back Order - Supplier

12 Dec 2018 02:21:10 PM Kate Griffiths See Attached Notes

13 Dec 2018 08:25:18 AM Catherine Spence Back Order - Supplier

Backorder 00006022 1114015 ORD95603

Issue ID #134180

Date Created 13/Dec/2018

Issued To: General

Completed Status: 17 Jan 2019

Stock Ref: 1114015 Opera A/c: 00006022

Order Number: ORD95603

Notes:

13 Dec 2018 08:25:24 AM Catherine Spence Back Order - Supplier

Backorder 00006022 1114015 ORD95969

Issue ID #135690

Date Created 08/Jan/2019

Issued To: General

Completed Status: 17 Jan 2019

Stock Ref: 1114015 Opera A/c: 00006022

Order Number: ORD95969

Notes:

08 Jan 2019 08:39:08 AM Catherine Spence Back Order - Supplier

1. 405000

Backorder 00006251 1114015 ORD93213

Issue ID #124481

Date Created 23/Jul/2018

Issued To: General

Completed Status: 23 Jul 2018

Stock Ref: 1114015 Opera A/c: 00006251

Order Number: ORD93213

Notes:

23 Jul 2018 08:42:28 AM Catherine Spence Shipping Mon 23 Jul 2018

Backorder 00006458 1114015 ORD95257

Issue ID #132807

Date Created 23/Nov/2018

Issued To: General

Completed Status: 17 Jan 2019

Stock Ref: 1114015 Opera A/c: 00006458

Order Number: ORD95257

Notes:

23 Nov 2018 08:54:00 AM Catherine Spence Back Order - Supplier

23 Nov 2018 01:12:43 PM Sarah Walton

Customer aware that we do not have stock. Waiting for SN to get back to me with whether we are ordering more or not. Will update customer once I know. They do not want part shipment.

06 Dec 2018 03:31:59 PM Sarah Walton

See Attached Notes

Please ship as soon as stock arrives, as the customers customer is chasing them on a daily basis.

They have been made aware of the lead time.

06 Dec 2018 03:32:00 PM Sarah Walton

Please ship as soon as stock arrives, as the customers customer is chasing them on a daily basis.

They have been made aware of the lead time.

31 Dec 2018 09:58:52 AM Catherine Spence Back Order - Supplier

Backorder 00006533 0110040 ORD96030

Issue ID #135908

Date Created 10/Jan/2019 Issued To: Kate Griffiths

Completed Status: 25 Jan 2019

Stock Ref: 0110040 Opera A/c: 00006533

Order Number: ORD96030

Notes:

10 Jan 2019 01:56:21 PM Kate Griffiths See Attached Notes

Production request completed for 0110437 x2. W/house request completed for 1134016 x5. 0110040 already on order. Customer aware and asked if would like part shipment. KG 10.1.19

15 Jan 2019 07:49:20 AM Catherine Spence Back Order - Supplier

17 Jan 2019 Kate Griffiths done 25 Jan 2019 08:06:42 AM Catherine Spence Shipping Fri 25 Jan 2019

405000

Backorder 00006673 1114016 ORD96735

Issue ID #140087

Date Created 11/Mar/2019

Issued To: General

Completed Status: 12 Mar 2019

Stock Ref: 1114016 Opera A/c: 00006673

Order Number: ORD96735

Notes:

11 Mar 2019 03:17:44 PM Sarah Walton See Attached Notes Also asked if these can be shipped too.

Backorder 00007392 1114015 ORD95873

Issue ID #135089

Date Created 31/Dec/2018

Issued To: General

Completed Status: 17 Jan 2019

Stock Ref: 1114015 Opera A/c: 00007392

Order Number: ORD95873

Notes:

31 Dec 2018 10:03:40 AM Catherine Spence Back Order - Supplier

1. 405000

Backorder 00007392 1114015 ORD98028

Issue ID #144715

Date Created 10/May/2019

Issued To: General

Completed Status: 13 May 2019

Stock Ref: 1114015 Opera A/c: 00007392

Order Number: ORD98028

Notes:

10 May 2019 08:25:02 AM Catherine Spence Shipping Fri 10 May 2019

144745

Backorder 00007518 1114015 ORD93253

Issue ID #124593

Date Created 24/Jul/2018

Issued To: General

Completed Status: 25 Jul 2018

Stock Ref: 1114015 Opera A/c: 00007518

Order Number: ORD93253

Notes:

24 Jul 2018 09:25:50 AM Zoey Teal Customer happy with order. OK to ship.

25 Jul 2018 08:06:38 AM Catherine Spence Shipping Wed 25 Jul 2018

Backorder 00007518 1114015 ORD94645

Issue ID #130540

Date Created 18/Oct/2018

Issued To: General

Completed Status: 19 Oct 2018

Stock Ref: 1114015 Opera A/c: 00007518

Order Number: ORD94645

Notes:

18 Oct 2018 04:17:58 PM Zoey Teal Quantities confirmed. OK to ship.

19 Oct 2018 08:07:00 AM Catherine Spence Shipping Fri 19 Oct 2018

Backorder 00007628 1114015 ORD93964

Issue ID #127516

Date Created 06/Sep/2018

Issued To: General

Completed Status: 12 Sep 2018

Stock Ref: 1114015 Opera A/c: 00007628

Order Number: ORD93964

Notes:

06 Sep 2018 11:38:56 AM Zoey Teal See Attached Notes

Emailed the customer for them to confirm how many packs of p/n 1114016 they would like as they have 2 lines of this on their order.

11 Sep 2018 01:29:00 PM Zoey Teal Customer confirmed. OK to ship.

12 Sep 2018 07:54:30 AM Catherine Spence Shipping Wed 12 Sep 2018

Backorder 00007628 1114015 ORD97941

Issue ID #144095

Date Created 03/May/2019

Issued To: General

Completed Status: 03 May 2019

Stock Ref: 1114015 Opera A/c: 00007628 Order Number: ORD97941

Notes:

03 May 2019 08:15:52 AM Catherine Spence Shipping Fri 03 May 2019

144005

Backorder 00007628 1114017 ORD97223

Issue ID #140660

Date Created 20/Mar/2019

Issued To: General

Completed Status: 20 Mar 2019

Stock Ref: 1114017 Opera A/c: 00007628

Order Number: ORD97223

Notes:

20 Mar 2019 08:52:28 AM Catherine Spence Shipping Wed 20 Mar 2019

Backorder 00007736 1114015 ORD92214

Issue ID #120413

Date Created 17/May/2018

Issued To: General

Completed Status: 27 Jun 2018

Stock Ref: 1114015 Opera A/c: 00007736

Order Number: ORD92214

Notes:

17 May 2018 07:38:03 AM Catherine Spence Shipping Thu 17 May 2018

1 100110

Backorder 00007736 1114015 ORD96676

Issue ID #138257

Date Created 15/Feb/2019

Issued To: General

Completed Status: 15 Feb 2019

Stock Ref: 1114015 Opera A/c: 00007736

Order Number: ORD96676

Notes:

15 Feb 2019 08:03:09 AM Catherine Spence Shipping Fri 15 Feb 2019

Backorder 00007736 1114015 ORD97983

Issue ID #144485

Date Created 08/May/2019

Issued To: General

Completed Status: 08 May 2019

Stock Ref: 1114015 Opera A/c: 00007736

Order Number: ORD97983

Notes:

08 May 2019 09:04:32 AM Catherine Spence Shipping Wed 08 May 2019

VIAMED Management Meeting - Other

Neomask CE certificate 2018-05-07

Issue ID #119796

Date Created 08/May/2018 Issued To: Derek Lamb

Completed Status: 27 Jul 2018

Linked Files

08 May 2018 CE Certificate - Ontecklong Medical Supply

Notes:

Added by Steve Nixon sent to Derek Lamb Ontecklong (Nanjing) Medical Supply Corporation Limited.

1114015 1114016 1114017

See Class I certificate attached. Produced by notified body NQA?

Questions:

- 1. Why Class I via notified body?
- 2. Is it genuine?
- 3. In the name of Ontecklong, but we buy from Sunnycare Medical Supply Co,

44 Jul 2019 Dorok Lomb

11 Jul 2018 Derek Lamb added to index,

NQA is a notified body by looks of things, but not been able to locate a certificate checker.

VIAMED Stock Meeting - Stock Processing

Neomask stock count

Issue ID #134599

Date Created 19/Dec/2018

Issued To: Derek Lamb

Completed Status: 20 Dec 2018

Notes:

Added by Robert Connor sent to Derek Lamb
INFORMATION ONLY ISSUE DO NOT ADD NOTES!
I have completed the stock count of the neomask stock in the main stock shelf. Physical count of the 1114017s is 120 and all of those have been scanned.

There are 3 barcodes left unaccounted for; ID numbers 1103917, 1103783, 1103771.

VIAMED Stock Meeting - Sale or Returns

Request Scanning Item to Sale or return

Issue ID #147518

Date Created 18/Jun/2019 Issued To: Catherine Spence Completed Status: 24 Jun 2019

Notes:

Added by Kate Griffiths sent to Catherine Spence
Please scan to Sale or Returns Location ID34132 Stock Reference: 1134014 x 1

21 Jun 2019 Catherine Spence will tray and make this today for you

24 Jun 2019 Catherine Spence 1372137

24 Jun 2019 Kate Griffiths

Issues:147518

done

VIAMED Stock Meeting - Sale or Returns

Request Scanning Item to Sale or return SOR868

Issue ID #125144

Date Created 01/Aug/2018 Issued To: Catherine Spence Completed Status: 03 Aug 2018

Notes:

Added by Zoey Teal sent to Catherine Spence Please scan to Sale or Returns Location ID34132 Stock Reference: 3 x 11340113 3 x 1134014

01 Aug 2018 Zoey Teal Sorry 3 x 1134011

03 Aug 2018 Catherine Spence

900814

900818

900815

1240758

1240757

1240756

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

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