



VIA MED

# NeoMask Phototherapy Eye Occlus

Light occluder which is for use with phototherapy light

Class I

Via Rule Rule 1 includes Eye oc  
Assesment Route Annex VII

Carried out by Derek Lamb  
13 / 06 / 18



# VIA MED

-  Stock References Review
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-  Design Changes Review
-  User Instructions Review
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# 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 Phototherapy Eye Mask - Large
1134016	NeoMask Phototherapy Eye - Medium
1134017	NeoMask Phototherapy Eye Mask - Small

Comments on Stock references review:

part number upto 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	C
1114016	NeoMask Phototherapy Eye	00009080	MODEL III	Sunnycare Medical Supply	C
1114017	NeoMask Phototherapy Eye	00009080	MODEL III	Sunnycare Medical Supply	C

Comments on Suppliers:

only the one supplier,  
however unable to get uotp date ISO certificate so have ceased buying until resolved

# Sales Information

Stock Reference	Description	2012	2013	2014	2015	2016	2017	2018
1114015	NeoMask Phototherapy Eye		18	132	201	43	113	79
1114016	NeoMask Phototherapy Eye		26	267	289	37	125	77
1114017	NeoMask Phototherapy Eye		26	99	163	19	135	32
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 Phototherapy Eye Mask - Large			11				
1134016	NeoMask Phototherapy Eye - Medium			2				
1134017	NeoMask Phototherapy Eye Mask - Small							

Comments on Sales Information:

units were selling but in limited numbers

# Countries Review

Country	2012	2013	2014	2015	2016	2017	2018
AL Algeria			[X]	[X]		[X]	
B Belgium		[X]	[X]	[X]			[X]
BU Bulgaria			[X]				[X]
CY Cyprus		[X]	[X]				[X]
DE Denmark						[X]	
F France		[X]	[X]	[X]	[X]	[X]	[X]
GR Greece			[X]				[X]
HK Hong Kong					[X]		
HU Hungary		[X]	[X]	[X]		[X]	
IN India		[X]			[X]		
IT Italy				[X]	[X]	[X]	
JO Jordan			[X]				
KE Kenya		[X]					
KU Kuwait			[X]				
LI Lithuania			[X]		[X]		[X]
ML Malta				[X]			
NE Netherlands				[X]			
OM Oman			[X]				
P Poland		[X]	[X]				
PO Portugal							[X]
RO Romania		[X]			[X]	[X]	
SER Serbia						[X]	[X]
SP Spain			[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:

units have been sample supplier to multiple countries, but limited sales

Comments on Risks with Sales to Countries:

no risks with countries

# Returns and Q.A. Fails Review

Comments on Returns:

no returns

Comments on Risks with Returns and Potential Re-work:

no returns

# Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no design changes

Comments on Risks with Design Changes:

no risks



# 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 user instructions

Comments on Risks User Instructions:

no risks with instruction manuals

# Labels Review

## Showing Documents Filed in F 7 / F 8 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
26085	NeoMask Phototherapy Eye Occlusion Shields Notified body certifi...	08/05/18
20412	Maxtec EyeMax EC Declaration of Conformance Unsigned	01/06/17
20409	NeoMask Phototherapy Eye Occlusion Shields EC Declaration of Con...	01/06/17
19775	NeoMask Phototherapy Eye Occlusion Shields Clinical Trials Repor...	04/05/17

Comments on Document Changes:

updated CE documents, and post market no other documents added

Comments on Risks with Document Changes:

no risks with documentation

# Internal Issues Review

Number of Issues reviewed: 26

Issue ID	Subject
102559	Office Meeting Sales Back Orders Review - By Customer Backorder 00005240 1114015 ORD88226
102670	Office Meeting Sales Back Orders Review - By Customer Backorder 00005240 1114015 ORD88245
119335	Office Meeting Sales Back Orders Review - By Customer Backorder 00006458 1114015 ORD91912
104304	Office Meeting Sales Back Orders Review - By Customer Backorder 00006459 1114015 ORD88575
121969	Office Meeting Sales Back Orders Review - By Customer Backorder 00007392 1114015 ORD92562
118030	Office Meeting Sales Back Orders Review - By Customer Backorder 00007518 1114015 ORD91652
116912	Office Meeting Sales Back Orders Review - By Customer Backorder 00007628 1114015 ORD91369
120413	Office Meeting Sales Back Orders Review - By Customer Backorder 00007736 1114015 ORD92214
99269	Office Meeting Sales Back Orders Review - By Customer Backorder 00007876 1114015 ORD87454
119796	Office Meeting Other Neomask CE certificate 2018-05-07
110153	Office Meeting Marketing Job Logger Neomask sample pack to send
98539	Office Meeting Back Order Report POR11294 1114015 //
98540	Office Meeting Back Order Report POR11294 1114016 //
98541	Office Meeting Back Order Report POR11294 1114017 //
118132	Office Meeting Sale or Returns Request Scanning Item to Sale or return
113693	Office Meeting Sale or Returns Request Scanning Item to Sale or return
110217	Office Meeting Sale or Returns Request Scanning Item to Sale or return
106027	Office Meeting Sale or Returns Request Scanning Item to Sale or return
105702	Office Meeting Sale or Returns Request Scanning Item to Sale or return
105106	Office Meeting Sale or Returns Request Scanning Item to Sale or return
102823	Office Meeting Sale or Returns Request Scanning Item to Sale or return
99834	Office Meeting Sale or Returns Request Scanning Item to Sale or return
99830	Office Meeting Sale or Returns Request Scanning Item to Sale or return
99829	Office Meeting Sale or Returns Request Scanning Item to Sale or return

Issue ID	Subject
96284	Office Meeting Sale or Returns Request Scanning Item to Sale or return
113829	Office Meeting Sale or Returns Request Scanning Item to Sale or return SOR839

Comments on Issues:

order processing issues only,  
no complaints / non conformances in the issue system

Comments on Risks with Issues:

no risks in the issue system

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00005240 1114015 ORD88226**

Issue ID #102559

Date Created 08/Sep/2017

Issued To: General

Completed Status: 11 Sep 2017

Stock Ref: 1114015

Opera A/c: 00005240

Order Number: ORD88226

---

Notes:

08 Sep 2017 08:18:37 AM Catherine Spence  
Shipping Fri 08 Sep 2017

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Issues:102559

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00005240 1114015 ORD88245**

Issue ID #102670

Date Created 11/Sep/2017

Issued To: General

Completed Status: 13 Sep 2017

Stock Ref: 1114015

Opera A/c: 00005240

Order Number: ORD88245

---

Notes:

11 Sep 2017 02:40:35 PM Sophie Lines  
£7.00 carriage charge. Zoey emailed.

12 Sep 2017 10:39:41 AM Katie Evans  
See Attached Notes  
Carriage accepted, please proceed

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Issues:102670

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00006458 1114015 ORD91912**

Issue ID #119335

Date Created 30/Apr/2018

Issued To: General

Completed Status: 30 Apr 2018

Stock Ref: 1114015

Opera A/c: 00006458

Order Number: ORD91912

---

Notes:

30 Apr 2018 07:56:27 AM Catherine Spence  
Shipping Mon 30 Apr 2018

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Issues:119335



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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00006459 1114015 ORD88575**

Issue ID #104304

Date Created 02/Oct/2017

Issued To: General

Completed Status: 02 Oct 2017

Stock Ref: 1114015

Opera A/c: 00006459

Order Number: ORD88575

---

Notes:

02 Oct 2017 08:08:23 AM Catherine Spence  
Shipping Mon 02 Oct 2017

---

Issues:104304

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00007392 1114015 ORD92562**

Issue ID #121969

Date Created 08/Jun/2018

Issued To: General

Completed Status: 08 Jun 2018

Stock Ref: 1114015

Opera A/c: 00007392

Order Number: ORD92562

---

Notes:

08 Jun 2018 08:16:26 AM Catherine Spence  
Shipping Fri 08 Jun 2018

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Issues:121969

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00007518 1114015 ORD91652**

Issue ID #118030

Date Created 12/Apr/2018

Issued To: General

Completed Status: 09 May 2018

Stock Ref: 1114015

Opera A/c: 00007518

Order Number: ORD91652

---

Notes:

12 Apr 2018 11:16:57 AM Catherine Spence  
See Attached Notes  
Ship with ord91653

09 May 2018 07:39:16 AM Catherine Spence  
Shipping Wed 09 May 2018

---

Issues:118030

---

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00007628 1114015 ORD91369**

Issue ID #116912

Date Created 26/Mar/2018

Issued To: General

Completed Status: 26 Mar 2018

Stock Ref: 1114015

Opera A/c: 00007628

Order Number: ORD91369

---

Notes:

26 Mar 2018 07:59:20 AM Catherine Spence  
Shipping Mon 26 Mar 2018

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Issues:116912

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00007736 1114015 ORD92214**

Issue ID #120413

Date Created 17/May/2018

Issued To: General

Completed Status: 17 May 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

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Issues:120413

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00007876 1114015 ORD87454**

Issue ID #99269

Date Created 24/Jul/2017

Issued To: General

Completed Status: 28 Jul 2017

Stock Ref: 1114015

Opera A/c: 00007876

Order Number: ORD87454

---

Notes:

24 Jul 2017 08:24:51 AM Catherine Spence  
Shipping Mon 24 Jul 2017

25 Jul 2017 07:56:32 AM Catherine Spence  
See Attached Notes  
waiting for documents

---

Issues:99269

---

VIAMED Management Meeting - Other  
**Neomask CE certificate 2018-05-07**

Issue ID #119796

Date Created 08/May/2018

Issued To: Derek Lamb

Completed Status: Still Outstanding

Linked Files

08 May 2018 CE Certificate - Ontecklong Medical Supply

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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,

---

Issues:119796

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Marketing Job Logger - Marketing Job Logger

**Neomask sample pack to send**

Issue ID #110153

Date Created 11/Dec/2017

Issued To: 73

Completed Status: Still Outstanding

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**Notes:**

Please can someone send the following sample pack via the SOR system tagged as `giving`: 1x 1134014 - Neomask sample pack. To:

Sister Helen Russel-Fisher  
Starlight Children`s Unit  
Wythenshawe Hospital  
Southmoor Road  
Wythenshawe  
M23 9LT

I will sign off the NHS Delivery Note, it will need a Director to authorise the SOR sample, so please ask Helen to sign off that. Letter just needs to say &#34;as per your discussion with Steve Hardaker, please find enclosed a sample pack of Neomask Phototherapy Masks for trial&#34; etc. Thanks.

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Issues:110153



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- Back Order Report

**POR11294 1114015 //**

Issue ID #98539

Date Created 11/Jul/2017

Issued To: Jonathan Connor

Completed Status: 11 Jul 2017

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Notes:

POR11294 1114015 Estimated ship to us date changed to / /

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Issues:98539

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- Back Order Report

**POR11294 1114016 //**

Issue ID #98540

Date Created 11/Jul/2017

Issued To: Jonathan Connor

Completed Status: 11 Jul 2017

---

Notes:

POR11294 1114016 Estimated ship to us date changed to / /

---

Issues:98540

---

- Back Order Report

**POR11294 1114017 //**

Issue ID #98541

Date Created 11/Jul/2017

Issued To: Jonathan Connor

Completed Status: 11 Jul 2017

---

Notes:

POR11294 1114017 Estimated ship to us date changed to / /

---

Issues:98541

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VIAMED Stock Meeting - Sale or Returns  
**Request Scanning Item to Sale or return**  
Issue ID #118132  
Date Created 13/Apr/2018  
Issued To: Catherine Spence  
Completed Status: 16 Apr 2018

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Notes:

Added by Sarah Walton sent to Catherine Spence  
Please scan to Sale or Returns Location ID34132 Stock Reference:  
3 x 1134011  
3 x 1134014  
3 x 4421200  
3 x 4421201  
3 x 4421202  
3 x 0021011

---

16 Apr 2018 Catherine Spence  
id:1240752  
1240751  
1240750  
1240496  
1240495  
1240494  
1240472  
859320  
1240474  
1240473  
859350  
859349  
859351  
859323  
859319  
859336  
859341  
859342

---

16 Apr 2018 Sarah Walton  
Done

---

Issues:118132

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VIAMED Stock Meeting - Sale or Returns

**Request Scanning Item to Sale or return**

Issue ID #113693

Date Created 02/Feb/2018

Issued To: Sophie Lines

Completed Status: 09 Feb 2018

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**Notes:**

Added by Sophie Lines sent to Sophie Lines

Please scan to Sale or Returns Location ID34132 Stock Reference: 1x 1134014 and 1x 1134011  
SOR838

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09 Feb 2018 Sophie Lines  
Done

---

09 Feb 2018 Sophie Lines

---

Issues:113693

---

VIAMED Stock Meeting - Sale or Returns

**Request Scanning Item to Sale or return**

Issue ID #110217

Date Created 12/Dec/2017

Issued To: Catherine Spence

Completed Status: 09 Jan 2018

---

**Notes:**

Added by Zoey Teal sent to Catherine Spence

Please scan to Sale or Returns Location ID34132 Stock Reference: 1 x 1134014 for SOR837

---

18 Dec 2017 Catherine Spence

these need making, is it for uk or export either way i need a price list for it please

---

18 Dec 2017 Zoey Teal

Next Action Changed From Catherine Spence To Jonathan ConnorIt is for UK please. J.C Cathy is away till Thursday, please can you make these if you have time please?

---

02 Jan 2018 Zoey Teal

Next Action Changed From Jonathan Connor To Catherine Spence Cathy please can you do this for me when you get chance?

---

08 Jan 2018 Catherine Spence

id: 1214180

---

09 Jan 2018 Zoey Teal

COMPLETED

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Issues:110217

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VIAMED Stock Meeting - Sale or Returns

**Request Scanning Item to Sale or return**

Issue ID #106027

Date Created 19/Oct/2017

Issued To: Catherine Spence

Completed Status: 23 Oct 2017

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**Notes:**

Added by Katie Evans sent to Catherine Spence

Please scan to Sale or Returns Location ID34132 Stock Reference: 1134014 x 3 and 0021011, 0021016, 3830005, 3830013, 3830021, 3830061 x 1 for SOR824

I have been asked to send a selection of Posey product samples. If any of the Posey sample packs are unavailable in a reasonable timescale, please disregard them.

I will bring some EUR distributor price lists over for the sample packs

---

20 Oct 2017 Katie Evans

SN has said that we are unable to send many Posey products to EUR distributors.

Please could we have 3 x 1134014, 1 x 0021011, 1 x 0021016 and 1 x 3830021

---

23 Oct 2017 Catherine Spence

ids: 811598,1194315,1194350,1194305,1194306,1194307

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23 Oct 2017 Katie Evans

Thank you

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Issues:106027

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VIAMED Stock Meeting - Sale or Returns

**Request Scanning Item to Sale or return**

Issue ID #105702

Date Created 18/Oct/2017

Issued To: Catherine Spence

Completed Status: 25 Oct 2017

---

**Notes:**

Added by Zoey Teal sent to Catherine Spence

Please scan to Sale or Returns Location ID34132 Stock Reference: 6 x 1134014 for export

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23 Oct 2017 Catherine Spence

ids: 1194308-1194313

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25 Oct 2017 Zoey Teal

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Issues:105702



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VIAMED Stock Meeting - Sale or Returns  
**Request Scanning Item to Sale or return**  
Issue ID #105106  
Date Created 11/Oct/2017  
Issued To: Catherine Spence  
Completed Status: 17 Oct 2017

---

Notes:

Added by Katie Evans sent to Catherine Spence  
Please scan to Sale or Returns Location ID34132 Stock Reference: 3 x 1134014 for SOR820

---

11 Oct 2017 Katie Evans  
Euro distributor price lists please

---

11 Oct 2017 Catherine Spence  
non in stock, will make some up tomorrow

---

17 Oct 2017 Katie Evans Please could you let me know if these are ready?

---

17 Oct 2017 Catherine Spence  
should be with in the hour

---

17 Oct 2017 Catherine Spence  
ids:1193657-659

---

17 Oct 2017 Katie Evans  
Thank you

---

Issues:105106

---

VIAMED Stock Meeting - Sale or Returns

**Request Scanning Item to Sale or return**

Issue ID #102823

Date Created 13/Sep/2017

Issued To: Catherine Spence

Completed Status: 13 Sep 2017

---

Notes:

Added by Sarah Walton sent to Catherine Spence

Please scan to Sale or Returns Location ID34132 Stock Reference:1134014

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13 Sep 2017 Catherine Spence

id: 1001598

---

13 Sep 2017 Sarah Walton

Done, thanks

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Issues:102823

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VIAMED Stock Meeting - Sale or Returns

**Request Scanning Item to Sale or return**

Issue ID #99834

Date Created 01/Aug/2017

Issued To: Catherine Spence

Completed Status: 02 Aug 2017

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**Notes:**

Added by Zoey Teal sent to Catherine Spence

Please scan to Sale or Returns Location ID34132 Stock Reference: 1 x 1134011, 1 x 1134014. Please remove GB price list. I will bring over some USD distributor price lists.

---

01 Aug 2017 Catherine Spence  
id: 1169794,1001597

---

02 Aug 2017 Zoey Teal  
COMPLETED

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Issues:99834

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VIAMED Stock Meeting - Sale or Returns

**Request Scanning Item to Sale or return**

Issue ID #99830

Date Created 01/Aug/2017

Issued To: Catherine Spence

Completed Status: 02 Aug 2017

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**Notes:**

Added by Katie Evans sent to Catherine Spence

Please scan to Sale or Returns Location ID34132 Stock Reference: 1 x 1134011 and 1 x 1134014 Please remove price list, I will bring some USD distributor ones over.

---

01 Aug 2017 Catherine Spence  
id: 1169793,1001596

---

02 Aug 2017 Katie Evans  
Thank you

---

Issues:99830

---

VIAMED Stock Meeting - Sale or Returns

**Request Scanning Item to Sale or return**

Issue ID #99829

Date Created 01/Aug/2017

Issued To: Catherine Spence

Completed Status: 01 Aug 2017

---

**Notes:**

Added by Katie Evans sent to Catherine Spence

Please scan to Sale or Returns Location ID34132 Stock Reference: 1 x 1134011 and 1 x 1134014 Please remove price list, I will bring some Euro distributor ones over

---

01 Aug 2017 Catherine Spence  
id: 1001595,1169792

---

01 Aug 2017 Katie Evans  
Thank you

---

Issues:99829

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VIAMED Stock Meeting - Sale or Returns

**Request Scanning Item to Sale or return**

Issue ID #96284

Date Created 08/Jun/2017

Issued To: Catherine Spence

Completed Status: 19 Jun 2017

---

**Notes:**

Added by Zoey Teal sent to Catherine Spence

Please scan to Sale or Returns Location ID34132 Stock Reference:1 x 1134011 1 x 1134014

---

12 Jun 2017 Catherine Spence

need to make 1134011, can u print a price list for it please

---

16 Jun 2017 Catherine Spence

id: 10001594,1094205

---

19 Jun 2017 Zoey Teal

COMPLETED

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Issues:96284

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VIAMED Stock Meeting - Sale or Returns

**Request Scanning Item to Sale or return SOR839**

Issue ID #113829

Date Created 05/Feb/2018

Issued To: Catherine Spence

Completed Status: 12 Feb 2018

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**Notes:**

Added by Sophie Lines sent to Catherine Spence

Please scan to Sale or Returns SOR839 Location ID34132 Stock Reference: 3x 1134014

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09 Feb 2018 Catherine Spence

id: 1223115,1223116,1223117

---

12 Feb 2018 Sophie Lines

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Issues:113829

# 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 :

difficult product line to search as class 1, and many public products described as eye masks.

no clinic reports found

## 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 :

difficult product line to search as class 1, and many public products described as eye masks.

no fda reports found