



VIA MED

COT Lids

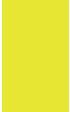

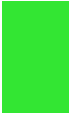








Acrylic Sheet: hinged with or without louvers, to be used in conjunction with a basinet, to retain heat and humidity.

Class I
Via Rule 1
Assesment Route Annex II
NBOG MD 0100

Carried out by Derek Lamb
25 / 10 / 18



VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
-  Countries Review
-  Returns Review
-  Design Changes Review
-  User Instructions Review
-  Labels Review
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-  Internal Issues Review
-  Clinical / FDA Incidents online search

Stock References Review

Stock Reference	Description
0392060	Leaflet - Cot Lids
0450120	Packing box - Cot Lids
0490051	Instructions for use - Viamed cot lids
PP8116	Cot Lid with Louvres *
PP8118	Cot lid special
PP8120	Cot lid upgrade kit - 08/03
PP8583	1 Piece Cot Lid With Stoppers*
PP8690	Cot lid
PP8711	Hoskins Cot Lid
PP8712	Bristol Maid Cot Lid
PP8713	Nesbit Evans Cot Lid
PP8776	Hoskins Cot Lid - One Piece
PP8777	Bristol Maid Cot Lid - One Piece
PP8778	Nesbit Evans Cot Lid - One Piece
PP8787	Bristol Maid Cot Lid
PP8788	Bristol Maid Cot Lid - One Piece
PP8789	Arjo-Huntleigh Cot Lid
PP8790	Arjo-Huntleigh Cot Lid - One Piece

Comments on Stock references review:

part number upto date

we have ceased selling these devices due to MHRA / BSI regulations and costs

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
PP8711	Hoskins Cot Lid	00009022	PP8711	Tanda Engineering Ltd	B
PP8712	Bristol Maid Cot Lid	00009022	PP8712	Tanda Engineering Ltd	B
PP8713	Nesbit Evans Cot Lid	00009022	PP8713	Tanda Engineering Ltd	B
PP8777	Bristol Maid Cot Lid - O	00009022	PP8777	Tanda Engineering Ltd	B
PP8778	Nesbit Evans Cot Lid - O	00009022	PP8778	Tanda Engineering Ltd	B
PP8787	Bristol Maid Cot Lid	00009022	PP8787	Tanda Engineering Ltd	B
PP8788	Bristol Maid Cot Lid - O	00009022	PP8788	Tanda Engineering Ltd	B
0450120	Packing box - Cot Lids	00009353	BOC531	Rajapack Ltd	A
PP8690	Cot lid	00011873	PP8690	Rossendale Plastics	E

Comments on Suppliers:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Sales Information

Stock Reference	Description	2012	2013	2014	2015	2016	2017	2018
0392060	Leaflet - Cot Lids							
0450120	Packing box - Cot Lids							
0490051	Instructions for use - Viamed cot lids							
PP8116	Cot Lid with Louvres *							
PP8118	Cot lid special							
PP8120	Cot lid upgrade kit - 08/03							
PP8583	1 Piece Cot Lid With Stoppers*							
PP8690	Cot lid							
PP8711	Hoskins Cot Lid	2	1			3	2	
PP8712	Bristol Maid Cot Lid	11	17	3	5	1	8	2
PP8713	Nesbit Evans Cot Lid	4	4	1	1	2		
PP8776	Hoskins Cot Lid - One Piece							
PP8777	Bristol Maid Cot Lid - O	4	6	6	12	18	4	6
PP8778	Nesbit Evans Cot Lid - O		1	2				
PP8787	Bristol Maid Cot Lid			1	4		4	
PP8788	Bristol Maid Cot Lid - O				1			2
PP8789	Arjo-Huntleigh Cot Lid							
PP8790	Arjo-Huntleigh Cot Lid - One Piece							

Comments on Sales Information:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Countries Review

Country	2012	2013	2014	2015	2016	2017	2018
SC Scotland				[X]	[X]		
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2012	2013	2014	2015	2016	2017	2018
PP8712	Unchecked - Returned To Stock	4						

Comments on Returns:

no failures ever for this device

we have ceased selling these devices due to MHRA / BSI regulations and costs

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
14537	PP8711 Hoskins Cot Lid User Instructions	10/11/14
14535	PP8712 Bristol Maid Cot Lid User Instructions	10/11/14
14533	PP8713 Nesbit EvansCot Lid User Instructions	10/11/14
14531	PP8776 Hoskins (One Piece) Cot Lid User Instructions	10/11/14
14529	PP8777 Bristol Maid (One Piece) Cot Lid User Instructions	10/11/14
14527	PP8778 Nesbit Evans (One Piece) Cot Lid User Instructions	10/11/14
14525	PP8787 Bristol Maid Cot Lid User Instructions	10/11/14
14523	PP8788 Bristol Maid (One Piece) Cot Lid User Instructions	10/11/14
14521	PP8790 Arjo Huntleigh (One Piece) Cot Lid User Instructions	10/11/14
14519	PP8789 Cot Lid for use with Arjo Huntleigh Cots Instructions for...	10/11/14
9637	Instruction For Use - Reusable Oxygen Hoods	13/12/11
7510	COT Lids Instructions for Use User Manual Cot Lids background i...	21/01/11
1898	Instructions For Use / Cleaning Cot Lids superceeded	18/06/07

Comments on User Instructions:

no manual changes

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
7523	COT Lids Labels	21/01/11
1899	Cot Lid Labels	18/06/07

Comments on Labels:

Comments on Risks Labels:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
24890	Cot lids clinical papers	17/01/18
22387	COT Lids Clinical Trials Reports Reviews and Post Market Surveil...	02/10/17

Comments on Document Changes:

Comments on Risks with Document Changes:

Internal Issues Review

Number of Issues reviewed: 11

Issue ID	Subject
101215	Office Meeting Sales Back Orders Review - By Customer Backorder 00003880 PP8777 ORD87902
105597	Office Meeting Sales Back Orders Review - By Customer Backorder 00003880 PP8777 ORD88811
107578	Office Meeting Sales Back Orders Review - By Customer Backorder 00003880 PP8777 ORD89226
100593	Office Meeting Sales Back Orders Review - By Customer Backorder 00003910 PP8712 ORD87796
107153	Office Meeting Sales Back Orders Review - By Customer Backorder 00003930 PP8712 ORD89112
120493	Office Meeting Sales Back Orders Review - By Customer Backorder 00005030 PP8788 ORD92199
108184	Office Meeting Non Conformance Issues Customer purchase order missed in the email inbox
107350	Office Meeting Back Order Report POR11504 PP8712 //
107351	Office Meeting Back Order Report POR11504 PP8777 //
110476	Office Meeting Back Order Report POR11518 PP8777 //
110469	Office Meeting Back Order Report POR11518 PP8777 //

Comments on Issues:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Comments on Risks with Issues:

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003880 PP8777 ORD87902

Issue ID #101215

Date Created 21/Aug/2017

Issued To: General

Completed Status: 09 Oct 2017

Stock Ref: PP8777

Opera A/c: 00003880

Order Number: ORD87902

Notes:

21 Aug 2017 08:34:08 AM Katie Evans

See Attached Notes

PO states 8-9 week lead time so customer is aware

29 Aug 2017 08:44:10 AM Catherine Spence

Back Order - Supplier

Issues:101215

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003880 PP8777 ORD88811

Issue ID #105597

Date Created 17/Oct/2017

Issued To: General

Completed Status: 03 Jan 2018

Stock Ref: PP8777

Opera A/c: 00003880

Order Number: ORD88811

Notes:

17 Oct 2017 08:09:49 AM Catherine Spence
Back Order - Supplier

20 Oct 2017 04:01:49 PM Sophie Lines
Aware of leadtime

Issues:105597

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003880 PP8777 ORD89226

Issue ID #107578

Date Created 08/Nov/2017

Issued To: General

Completed Status: 03 Jan 2018

Stock Ref: PP8777

Opera A/c: 00003880

Order Number: ORD89226

Notes:

08 Nov 2017 08:23:23 AM Catherine Spence
Back Order - Supplier

04 Dec 2017 08:41:54 AM Zoey Teal
Aware of lead time

Issues:107578

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003910 PP8712 ORD87796

Issue ID #100593

Date Created 11/Aug/2017

Issued To: General

Completed Status: 09 Oct 2017

Stock Ref: PP8712

Opera A/c: 00003910

Order Number: ORD87796

Notes:

11 Aug 2017 01:53:06 PM Sophie Lines
they have sent in another order for 3x PP8712 - emailed to check whether the order sent yesterday (200513856) is still required or if this a duplicate? SJH confirmed to supply PP8712 not PP8787

14 Aug 2017 01:29:13 PM Sophie Lines
Tried to call Michael Pattison but number rings out. Re-sent email regarding both these orders - I think one is a duplicate

18 Aug 2017 04:38:35 PM Sophie Lines
Chased up

21 Aug 2017 11:28:10 AM Sophie Lines
Okay to proceed

29 Aug 2017 08:47:09 AM Catherine Spence
Back Order - Supplier

04 Sep 2017 01:40:30 PM Sophie Lines
Customer is aware of leadtime

Issues:100593

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00003930 PP8712 ORD89112

Issue ID #107153

Date Created 02/Nov/2017

Issued To: General

Completed Status: 03 Jan 2018

Stock Ref: PP8712

Opera A/c: 00003930

Order Number: ORD89112

Notes:

02 Nov 2017 08:14:17 AM Catherine Spence
Back Order - Supplier

03 Nov 2017 03:13:57 PM Zoey Teal
Aware of lead time

Issues:107153

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00005030 PP8788 ORD92199

Issue ID #120493

Date Created 18/May/2018

Issued To: General

Completed Status: 21 May 2018

Stock Ref: PP8788

Opera A/c: 00005030

Order Number: ORD92199

Notes:

18 May 2018 07:20:13 AM Catherine Spence
Shipping Fri 18 May 2018

18 May 2018 02:05:05 PM Catherine Spence
Testing/QA
To Box

Issues:120493

Non Conformance Issues - Non Conformance Issues

Customer purchase order missed in the email inbox

Issue ID #108184

Date Created 14/Nov/2017

Issued To: Helen Lamb

Completed Status: 08 Feb 2018

Notes:

Added by Steve Hardaker sent to Helen Lamb

Tony Crawford from Poole Hospital called, chasing an order for 4x PP8712 Bristol Maid cot lids that he placed on 22/8/17, P631783. He didnt chase it up sooner as he was aware of the long lead-time and, as the order was placed via the GHX system, they got an automated response saying that we have received it.

The email accompanying the purchase order can be seen in the main inbox but we had not processed it, subject line - Purchase Order No: P631783 from : Poole Hospital NHS Foundation Trust. It`s now on the system. Perhaps additional checks are required on the email inbox?

16 Nov 2017 Helen Lamb

Priority Changed From 5 To 10

08 Feb 2018 Helen Lamb

Thank you for letting me know. I am doing a non conformance review and this will be included.

08 Feb 2018 Steve Hardaker

Issues:108184

- Back Order Report

POR11504 PP8712 //

Issue ID #107350

Date Created 06/Nov/2017

Issued To: Jonathan Connor

Completed Status: 06 Nov 2017

Notes:

POR11504 PP8712 Estimated ship to us date changed to / /

Issues:107350

- Back Order Report

POR11504 PP8777 //

Issue ID #107351

Date Created 06/Nov/2017

Issued To: Jonathan Connor

Completed Status: 06 Nov 2017

Notes:

POR11504 PP8777 Estimated ship to us date changed to / /

Issues:107351

- Back Order Report

POR11518 PP8777 //

Issue ID #110476

Date Created 15/Dec/2017

Issued To: Jonathan Connor

Completed Status: 15 Dec 2017

Notes:

POR11518 PP8777 Estimated ship to us date changed to / /

Issues:110476

- Back Order Report

POR11518 PP8777 //

Issue ID #110469

Date Created 15/Dec/2017

Issued To: Jonathan Connor

Completed Status: 15 Dec 2017

Notes:

POR11518 PP8777 Estimated ship to us date changed to / /

Issues:110469

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 :

we have ceased selling these devices due to MHRA / BSI regulations and costs

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 :

we have ceased selling these devices due to MHRA / BSI regulations and costs