

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 18 / 11 / 19



- Stock References Review
- Supplier Review
- Sales Review
- Countries Review
- Returns Review
- Design Changes Review
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- Labels Review
- Document Updates Review
- 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 correct, no longer in production

Supplier Review

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

Comments on Suppliers:

no longer in production

Sales Information

Stock Reference	Description	2013	2014	2015	2016	2017	2018	2019
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	1			3	2		
PP8712	Bristol Maid Cot Lid	17	3	5	1	8	2	
PP8713	Nesbit Evans Cot Lid	4	1	1	2			
PP8776	Hoskins Cot Lid - One Piece							
PP8777	Bristol Maid Cot Lid - O	6	6	12	18	4	6	
PP8778	Nesbit Evans Cot Lid - O	1	2					
PP8787	Bristol Maid Cot Lid		1	4		4	1	
PP8788	Bristol Maid Cot Lid - O			1			4	1
PP8789	Arjo-Huntleigh Cot Lid							
PP8790	Arjo-Huntleigh Cot Lid - One Piece							

Comments on Sales Information:

no longer in production

Countries Review

Country	2013	2014	2015	2016	2017	2018	2019
SC Scotland			[X]	[X]			
UK United Kingdom	[X]						

Comments on Sales to Countries:

no longer in production

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2013	2014	2015	2016	2017	2018	2019
PP8712	Unchecked - Returned To Stock							

Comments on Returns:

no longer in production

Comments on Risks with Returns and Potential Re-work:

no reworks

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 changes

Comments on Risks User Instructions:

Labels Review

Showing Documents Filed in F7/F8 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:

no changes

Comments on Risks Labels:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
28776	Viamed Certification ISO 13485:2016 MD78787	26/02/19
27924	COT Lids Clinical Trials Reports Reviews and Post Market Surveil	25/10/18

Comments on Document Changes:

no document changes aside from this report itself

Comments on Risks with Document Changes:

Internal Issues Review Number of Issues reviewed: 4

Issue ID	Subject
134796	Xero Accounts Upgrade Sales Back Orders Review - By Customer Backorder 00000290 PP8787 ORD95824
135858	Xero Accounts Upgrade Sales Back Orders Review - By Customer Backorder 00001040 PP8788 ORD96038
134443	Xero Accounts Upgrade Price Lists UK Oxygen hood pricing incorrect in Intrastats
153822	Xero Accounts Upgrade Web Site Updates Web Site Question ID 7869

Comments on Issues:

nothing in the system

Comments on Risks with Issues:

no

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00000290 PP8787 ORD95824

Issue ID #134796

Date Created 21/Dec/2018

Issued To: General

Completed Status: 24 Dec 2018

Stock Ref: PP8787 Opera A/c: 00000290

Order Number: ORD95824

Notes:

21 Dec 2018 01:25:51 PM Zoey Teal Customer happy to take just the one lid in stock.

Issues:134796

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00001040 PP8788 ORD96038

Issue ID #135858

Date Created 10/Jan/2019

Issued To: General

Completed Status: 11 Jan 2019

Stock Ref: PP8788 Opera A/c: 00001040

Order Number: ORD96038

Notes:

10 Jan 2019 08:32:09 AM Catherine Spence Shipping Thu 10 Jan 2019

L. . . 405050

Issues:135858

VIAMED Sales And Marketing - Price Lists UK

Oxygen hood pricing incorrect in Intrastats

Issue ID #134443

Date Created 17/Dec/2018

Issued To: Catrin Hird

Completed Status: 18 Dec 2018

Notes:

Added by Steve Hardaker sent to Catrin Hird

There seems to be an error on some of the Intrastats pricing for the acrylic items on the recent mailshot.

Milton Keynes Hospital got the mailing and enquired about PP8788 and PP8526. On both of these, the prices listed on Intrastats appears to be 25% off the price already discounted by 15% previously, instead of 25% off the List price.

I mentioned it to the office staff today but is this something you can correct or does it need Steve or Derek to fix?

18 Dec 2018 Catrin Hird
Updated, thanks for spotting. Will ask DL to push prices through now.

18 Dec 2018 Steve Hardaker

Issues:134443

Non Conforming Stock Transfers. (QC19) - Web Site Updates

Web Site Question ID 7869

Issue ID #153822

Date Created 09/Sep/2019 Issued To: Kate Griffiths

Completed Status: 09 Sep 2019

Notes:

Web Site Question ID 7869 09/09/19 sharon.roberts11@nhs.net Information Request to Viamed Limited at the https://www.viamed.co.uk/uk/ WebSite

Sharon Roberts Russells Hall Hospital Maternity sharon.roberts11@nhs.net United Kingdom EU Type: General

I am looking to order cot lids for our cribs on the maternity department. Our Neonatal Department ordered some in 2013. The following were the order numbers: PP8712/PP8787

Do you still supply these? If so what are the recent order numbers?

Request further Information on

09 Sep 2019 Kate Griffiths

replied that we can no longer supply these, as per SH. KG 9.9.19

Issues:153822

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 :

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem: No Do any of the Results indicate outdated Technology: Comments on Clinical Search: