



VIA MED

COT Lids

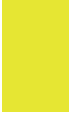
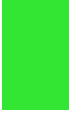
Acrylic Sheet: hinged with or without louvers, to be used in conjunction with a basinet, to retain heat and humidity.

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

Carried out by Derek Lamb
18 / 08 / 16



VIA MED

-  Stock References Review
-  Supplier Review
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-  Design Changes Review
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-  Internal Issues Review
-  Clinical / FDA Incidents online search
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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

Supplier Review

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

Comments on Suppliers:

supplier review up to date

Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
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		3	2	1			2
PP8712	Bristol Maid Cot Lid	34	17	11	17	3	5	1
PP8713	Nesbit Evans Cot Lid		2	4	4	1	1	2
PP8776	Hoskins Cot Lid - One Piece							
PP8777	Bristol Maid Cot Lid - O			4	6	6	12	16
PP8778	Nesbit Evans Cot Lid - O				1	2		
PP8787	Bristol Maid Cot Lid					1	4	
PP8788	Bristol Maid Cot Lid - O						1	
PP8789	Arjo-Huntleigh Cot Lid							
PP8790	Arjo-Huntleigh Cot Lid - One Piece							

Comments on Sales Information:

units still selling,

Countries Review

Country	2010	2011	2012	2013	2014	2015	2016
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

Only selling to the UK

Comments on Risks with Sales to Countries:

n/a

Returns Review

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
PP8712	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

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

Comments on Labels:

Outer box label (handle with care) added to outer packaging

Comments on Risks Labels:

n/a

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
16792	Head Box Oxygen Hoods Labels	20/04/16
16176	Viamed Certification ISO 13485:2003 MD78787	12/01/16
15653	Cot Lids Leaflets (email)	18/09/15
15423	COT Lids Risk analysis reports (3)	11/08/15
15418	PPE Equipment	11/08/15
15296	COT Lids EC Declaration of Conformance	29/07/15
15183	No risks disposal	21/07/15
15114	COT Lids Clinical Trials Reports Reviews and Post Market Surveil...	25/06/15

Comments on Document Changes:

declaration conformance updated to include all part numbers rather than individual documents per partnumber

Comments on Risks with Document Changes:

no risks with changes

Internal Issues Review

Number of Issues reviewed: 35

Issue ID	Subject
76352	Backorder 00000290 PP8711 ORD81723
63498	Backorder 00001040 PP8713 ORD76373
63828	Backorder 00001040 PP8787 ORD76373
66028	Backorder 00002400 PP8713 ORD77916
71173	Backorder 00002400 PP8713 ORD80111
72444	Backorder 00003668 PP8777 ORD80624
63894	Backorder 00003880 PP8777 ORD76703
66777	Backorder 00003880 PP8777 ORD78305
68709	Backorder 00003880 PP8777 ORD79192
70474	Backorder 00003880 PP8777 ORD79881
72058	Backorder 00003880 PP8777 ORD80253
59674	Backorder 00003930 PP8712 ORD74523
62461	Backorder 00004491 PP8712 ORD75929
62575	Backorder 00004491 PP8787 ORD75929
72766	Backorder 00005030 PP8777 ORD80733
66387	Backorder 00005250 PP8711 ORD78074
66388	Backorder 00005250 PP8712 ORD78074
66417	Cot lids
66416	Cot lids
38589	Plastics Photography
70446	POR10717 PP8777 //
70450	POR10717 PP8777 26/05/2016
70449	POR10717 PP8777 26/5-/6
71441	POR10736 PP8713 //
71166	POR10736 PP8713 //
71446	POR10746 PP8777 //
71448	POR10746 PP8777 16/06/2016
71447	POR10746 PP8777 16/6-/6
72520	POR10784 PP8777 //
73157	POR10793 PP8777 //
73154	POR10793 PP8777 //
76859	POR10883 PP8711 //
76832	POR10883 PP8711 //
57874	PP8788 - Bristol Maid 1-piece cot lid (latest design)
66384	Tanda Engineering

Comments on Issues:

Only supply / order issues in the system

Comments on Risks with Issues:

n/a

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 :

Nothing found on the internet relating to cot lids.
its a simple lid,

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 :

Nothing found on the internet relating to cot lids.
its a simple lid,