



21/May/2013

## Post market Surveillance and Risk Assessment Re-evaluation

COT Lids
Viamed Product
Post market Surveillance
Risk Assessment
Stock References Review
Supplier Review
Sales Review
Country Sales Review
Stock Returns Review
Design Changes Review
User Manuals Review
Labels Review
Document Updates Review
Internal Issues Review
Clinical Information Review
FDA Incidents Review
Carried out by Derek Lamb on 21 / 05 / 13

## Stock References Reviewed

Stock Reference	Description
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	Nesbitt Evans Cot Lid
PP8776	Hoskins Cot Lid - One Piece
PP8777	Bristol Maid Cot Lid - One Piece
PP8778	Nesbitt Evans Cot Lid - One Piece

Comments on Stock references review:

## Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
PP8711	Hoskins Cot Lid	00009022	Tanda Engineering Ltd	A
PP8712	Bristol Maid Cot Lid	00009022	Tanda Engineering Ltd	A
PP8713	Nesbitt Evans Cot Lid	00009022	Tanda Engineering Ltd	A
PP8777	Bristol Maid Cot Lid - One Piece	00009022	Tanda Engineering Ltd	A
PP8778	Nesbitt Evans Cot Lid - One Piece	00009022	Tanda Engineering Ltd	A
PP8690	Cot lid	00011873	Rossendale Plastics	B

Comments on Suppliers:

only use tanda currently

## Sales Information

Stock Reference	Description	2007	2008	2009	2010	2011	2012	2013
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	10	7			2	2	
PP8712	Bristol Maid Cot Lid	15	15	18	20	12	11	9
PP8713	Nesbitt Evans Cot Lid	6	1			2	4	4
PP8776	Hoskins Cot Lid - One Piece							
PP8777	Bristol Maid Cot Lid - One Piece						4	
PP8778	Nesbitt Evans Cot Lid - One Piece							

Comments on Sales Information:

units still selling, looking like 2013 is picking up in numbers

## New Countries

Country	2007	2008	2009	2010	2011	2012	2013
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

only sell the U.K.

Comments on Risks with Sales to Countries:

No Applicable

# Returns Information

Comments on Returns:

Zero returns Ever,  
although not a product thats likly to be returned

Comments on Risks with Returns and Potential Re-work:

No Applicable

## Design Changes / Product Changes

### Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No design modifications

Comments on Risks with Design Changes:

No Applicable

## User Instructions

### Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
9637	Instruction For Use - Reusable Oxygen Hoods	13/12/11
9486	COT Lids Instructions for Use User Manual Instructions for Use ...	18/10/11
7551	COT Lids Instructions for Use User Manual User Instructions Cot...	21/01/11
7510	COT Lids Instructions for Use User Manual Cot Lids background i...	21/01/11
1898	Instructions For Use / Cleaning Cot Lids	18/06/07

Comments on User Instructions:

No changes to instruction manuals

Comments on Risks User Instructions:

No Applicable



## Labels

### Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
9169	No accessory labels	18/10/11
7523	COT Lids Labels	21/01/11
7498	Head Box Oxygen Hoods Labels	21/01/11
1899	Cot Lid Labels	18/06/07

Comments on Labels:

Comments on Risks Labels:

No Applicable

## Documentation Updates / Changes

Comments on Document Changes:

no significant changes to documents,

Comments on Risks with Document Changes:

No Applicable

## Review of Issues

Number of Issues reviewed: 16

Issue ID	Subject
42798	SOR554 - Northampton General
39741	Returned Items SOR512
38747	Returned Items SOR527
37603	Kings Mill Hospital - Special Cot Lid - PP8713
37502	
35218	Request Scanning Item to Sale or return
37062	Risk Analysis - One Piece Cot lids
41379	Cot lid instructions need revising
39971	Cot lid instructions need revising
41365	Backorder 00000016 PP8713 ORD60975
37463	Backorder 00005030 PP8713 ORD57962
37346	Tanda Delivery
37345	Tanda Delivery
37344	Tanda Delivery
34453	PP8712 - please advise when received
38589	Plastics Photography

Comments on Issues:

41379 BS EN ISO 13485:2003 Document Control Amendments needed Document Control Amendments needed,  
Read Issue, seems instructions and design needs checking against current nesbit cots,

Comments on Risks with Issues:

41379 BS EN ISO 13485:2003 Document Control Amendments needed Document Control Amendments needed

No a user / patient risk. but a concern for potential breakage.  
Issue is in progress

## Review of online clinical reports

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 : No

Comments on Clinical Search :