



12/Mar/2012

## 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
Document Updates Review
Internal Issues Review
Clinical Information Review
FDA Incidents Review
Carried out by Derek Lamb on 12 / 03 / 12

## 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

Comments on Stock references review:

No new part numbers have been added,

## 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
PP8690	Cot lid	00011873	Rossendale Plastics	B

Comments on Suppliers:

Rossendale Plastics - old supplier, no only user Tanda,PP86900 - No sales since 2002, replaced with the 3 tanda models.

## Sales Information

Stock Reference	Description	2006	2007	2008	2009	2010	2011	2012
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	10	7			2	
PP8712	Bristol Maid Cot Lid	3	15	15	18	20	12	3
PP8713	Nesbitt Evans Cot Lid	8	6	1			2	

Comments on Sales Information:

Still sell units consistantlt

## New Countries

Country	2006	2007	2008	2009	2010	2011	2012
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

Only sell to the UK. so no NEW countries

Comments on Risks with Sales to Countries:

Only sell to the UK. so no NEW countries

## Returns Information

Comments on Returns:

No returns recorded for this product.

Comments on Risks with Returns and Potential Re-work:

No returns recorded for this product.

## Design Changes / Product Changes

### Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No New documentation since last review

Comments on Risks with Design Changes:

No New documentation since last review

## Documentation updates / Changes

Document ID	Description
9637	Instruction For Use - Reusable Oxygen Hoods
9490	COT Lids Risk analysis reports
9489	COT Lids Product Changes Background
9488	COT Lids Essential requirements
9487	COT Lids EC Declaration of Conformance 1994 blank
9486	COT Lids Instructions for Use User Manual Instructions for Use ...
9457	Generic CE File Attached to All Medicinal Substances None
9456	Generic CE File Attached to All Ionising Radiation None
9455	Carcinogenic Substances
9357	Head Box Oxygen Hoods Pre-Clinical Trials Data
9177	Heat Shields Product Life
9169	No accessory labels
9168	No service procedures required
9164	CE No Maintenance manual required
9145	No Clinical Trials
9140	Notified Body Certificate Not Required
9098	No 510k Required
9080	No Animal Tissues No Animal Substances
9056	VM3COP52.02 Cotlids Packing procedure
9025	Cot Lid Location of Documents Amendment Control
8315	Human Blood & derivatives Statement of non use
8199	Plastics Oxygen Therapy Chair Specifications of Materials
8043	Machinery Directive Not Applicable
8017	COT Lids Specifications of Materials 2002 Specification of mater...
7974	Cleaning Instructions Common Plastics 2002
7945	Cot Lid EN ISO 14971:2001 Annex A
7944	COT Lids Preliminary drawings Dwg Special P8690
7943	COT Lids Analysis of complaints Stockport Photographs
7942	COT Lids Work Instructions and Tests
7940	COT Lids EN ISO 14971:2001 Annex D
7936	COT Lids Risk analysis certificate
7934	COT Lids Product Life
7933	COT Lids Product Changes Cot Lid Product Changes 2005
7932	COT Lids MHRA Correspondence
7931	COT Lids Classification rationale classification rationale 2005
7930	COT Lids Classification rationale classification 2005
7929	COT Lids Description of Device
7751	Training Information
7686	Description of Accessories
7667	Nova Oxygen Tents Leakage and Liquid damage
7594	Plastics Pre-Design Risk analysis report
7590	Plastics Residual Risks
7588	Plastics Leakage and Liquid damage

Comments on Document Changes:



a Few documents were brought up to date, for latest CE file regulations, Cleaning instructions were updated, Packaging procedures were reviewed and updated

Comments on Risks with Document Changes:

No risks identified with document updates

## Review of Issues

Number of Issues reviewed: 16

Comments on Issues:

4 Issues raised regarding units, Relating to Purchase orders, Sale or Return Trials

Comments on Risks with Issues:

No Risks identified with Issues

## 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 :

Nothing found on google

## 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 google