



16/May/2012

Post market Surveillance and Risk Assessment Re-evaluation

Oxygen Hoods
Viamed Product
Post market Surveillance
Risk Assessment
Stock References Review
Supplier Review
Sales Review
Country Sales Review
Stock Returns Review
Design Changes Review
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Internal Issues Review
Clinical Information Review
FDA Incidents Review
Carried out by Derek Lamb on 16 / 05 / 12

Stock References Reviewed

Stock Reference	Description
PP8000	Oxygen Hood - Size 1 with sliding front
PP8020	Oxygen Hood - Size 1 with sliding front
PP8050	Oxygen Hood - Size 2 with sliding front
PP8055	Oxygen Hood - Size 2 with sliding front
PP8060	Oxygen Hood - Size 3 with sliding front
PP8065	Oxygen Hood - Size 3 with sliding front
PP8509	Phototherapy Light Shield/Oxygen Hood.
PP8533	Phototherapy Light Shield/Oxygen Hood.
PP8540	Phototherapy Light Shield/Oxygen Hood.
PP8562	Phototherapy Light Shield/Oxygen Hood.
PP8565	Phototherapy Light Shield/Oxygen Hood.
PP8589	Oxygen Hood - Size 4 with sliding front
PP8687	Oxygen hood - special. With side doors.
PP8715	Oxygen Hood - Size 4 with sliding front
PP8729	Oxygen hood - special.
PP8730	Oxygen hood - special.
PP8744	Oxygen hood - special.
PP8746	Oxygen hood - special.
PP8747	Oxygen hood - special.
PP8748	Oxygen hood - special.
PP8752	Oxygen hood - special.
PP8753	Oxygen hood - special.
PP8754	Oxygen hood - special.
PP8755	Oxygen hood - special.
PP8756	Oxygen hood - special.
PP8757	Oxygen hood - special.
PP8758	Oxygen hood - special.
PP8759	Oxygen hood - special.
PP8760	Oxygen hood - special.
PP8771	Oxygen Hood - Special
PP8772	Oxygen hood - special.
PP8773	Oxygen hood - special.
PP8774	Oxygen Hood - special.
PP8775	Oxygen Hood - special.

Comments on Stock references review:

no new numbers

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
PP8000	Oxygen Hood - Size 1 with sliding front	00009022	Tanda Engineering Ltd	A
PP8020	Oxygen Hood - Size 1 with sliding front	00009022	Tanda Engineering Ltd	A
PP8050	Oxygen Hood - Size 2 with sliding front	00009022	Tanda Engineering Ltd	A
PP8055	Oxygen Hood - Size 2 with sliding front	00009022	Tanda Engineering Ltd	A
PP8060	Oxygen Hood - Size 3 with sliding front	00009022	Tanda Engineering Ltd	A
PP8065	Oxygen Hood - Size 3 with sliding front	00009022	Tanda Engineering Ltd	A
PP8509	Phototherapy Light Shield/Oxygen Hood.	00009022	Tanda Engineering Ltd	A
PP8533	Phototherapy Light Shield/Oxygen Hood.	00009022	Tanda Engineering Ltd	A
PP8562	Phototherapy Light Shield/Oxygen Hood.	00009022	Tanda Engineering Ltd	A
PP8589	Oxygen Hood - Size 4 with sliding front	00009022	Tanda Engineering Ltd	A
PP8687	Oxygen hood - special. With side doors.	00009022	Tanda Engineering Ltd	A
PP8715	Oxygen Hood - Size 4 with sliding front	00009022	Tanda Engineering Ltd	A
PP8729	Oxygen hood - special.	00009022	Tanda Engineering Ltd	A
PP8730	Oxygen hood - special.	00009022	Tanda Engineering Ltd	A
PP8744	Oxygen hood - special.	00009022	Tanda Engineering Ltd	A
PP8746	Oxygen hood - special.	00009022	Tanda Engineering Ltd	A
PP8747	Oxygen hood - special.	00009022	Tanda Engineering Ltd	A
PP8748	Oxygen hood - special.	00009022	Tanda Engineering Ltd	A
PP8754	Oxygen hood - special.	00009022	Tanda Engineering Ltd	A
PP8755	Oxygen hood - special.	00009022	Tanda Engineering Ltd	A
PP8756	Oxygen hood - special.	00009022	Tanda Engineering Ltd	A
PP8757	Oxygen hood - special.	00009022	Tanda Engineering Ltd	A
PP8758	Oxygen hood - special.	00009022	Tanda Engineering Ltd	A
PP8759	Oxygen hood - special.	00009022	Tanda Engineering Ltd	A
PP8760	Oxygen hood - special.	00009022	Tanda Engineering Ltd	A
PP8771	Oxygen Hood - Special	00009022	Tanda Engineering Ltd	A
PP8774	Oxygen Hood - special.	00009022	Tanda Engineering Ltd	A
PP8775	Oxygen Hood - special.	00009022	Tanda Engineering Ltd	A

Comments on Suppliers:

supplier information uptodate

Sales Information

Stock Reference	Description	2006	2007	2008	2009	2010	2011	2012
PP8000	Oxygen Hood - Size 1 with sliding front	9	8	5	11	19	9	2
PP8020	Oxygen Hood - Size 1 with sliding front	2	4	4	3	2	8	
PP8050	Oxygen Hood - Size 2 with sliding front	16	9	32	25	8	15	76
PP8055	Oxygen Hood - Size 2 with sliding front	9	3	4	6	1	7	1
PP8060	Oxygen Hood - Size 3 with sliding front	35	18	31	56	13	12	15
PP8065	Oxygen Hood - Size 3 with sliding front	6	6	8	14	12	5	11
PP8509	Phototherapy Light Shield/Oxygen Hood.		8		2	9	1	
PP8533	Phototherapy Light Shield/Oxygen Hood.	4	4		2	1	0	
PP8540	Phototherapy Light Shield/Oxygen Hood.							
PP8562	Phototherapy Light Shield/Oxygen Hood.	2	4					
PP8565	Phototherapy Light Shield/Oxygen Hood.							
PP8589	Oxygen Hood - Size 4 with sliding front	43	35	30	71	30	11	8
PP8687	Oxygen hood - special. With side doors.			5	1	6		2
PP8715	Oxygen Hood - Size 4 with sliding front	22	13	10	14	10	13	
PP8729	Oxygen hood - special.							
PP8730	Oxygen hood - special.							
PP8744	Oxygen hood - special.	3						
PP8746	Oxygen hood - special.	1						
PP8747	Oxygen hood - special.	1						
PP8748	Oxygen hood - special.		1					
PP8752	Oxygen hood - special.							
PP8753	Oxygen hood - special.							
PP8754	Oxygen hood - special.			4				
PP8755	Oxygen hood - special.							
PP8756	Oxygen hood - special.							
PP8757	Oxygen hood - special.		1	0				
PP8758	Oxygen hood - special.		1	0				
PP8759	Oxygen hood - special.							
PP8760	Oxygen hood - special.							
PP8771	Oxygen Hood - Special				1	3	11	
PP8772	Oxygen hood - special.							
PP8773	Oxygen hood - special.							
PP8774	Oxygen Hood - special.						1	2
PP8775	Oxygen Hood - special.						1	

Comments on Sales Information:

units are still selling

New Countries

Country	2006	2007	2008	2009	2010	2011	2012
AU Austria				[X]			
B Belgium	[X]	[X]	[X]	[X]	[X]	[X]	[X]
CHA Channel Islands							
GI Gibraltar							
GR Greece	[X]				[X]		
IRE Ireland		[X]	[X]	[X]		[X]	
IT Italy			[X]	[X]			
JO Jordan	[X]						
MA Malaysia	[X]						
MAU Mauritius			[X]	[X]	[X]	[X]	
MO Morrocco						[X]	
NE Netherlands					[X]		
OM Oman	[X]		[X]	[X]	[X]	[X]	
P Poland				[X]	[X]	[X]	
PO Portugal							
Q Qatar							[X]
RO Romania					[X]		
SP Spain		[X]	[X]	[X]	[X]	[X]	[X]
SW Sweden		[X]					
T Turkey		[X]		[X]			
UAE U.A.E.	[X]	[X]					
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

new country Qatar

Comments on Risks with Sales to Countries:

no risk associated with new countrys

Returns Information

Stock Reference	Fault	2006	2007	2008	2009	2010	2011	2012
PP8589	Unable to repair				1			
PP8757	No Fault Return to Stock							
PP8758	No Fault Return to Stock							

Comments on Returns:

no returns

Comments on Risks with Returns and Potential Re-work:

n/a

Design Changes / Product Changes

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no new documentation,

Comments on Risks with Design Changes:

n/a

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

Comments on User Instructions:

instructions updated and pdf ed

Comments on Risks User Instructions:

no risks with instruction manuals

Labels

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
9526	Oxygen Hoods Labels 0430011	18/10/11
9169	No accessory labels	18/10/11
8523	Oxygen Hoods Labels	13/07/11
8521	Oxygen Hoods Labels 0430010	13/07/11
7498	Head Box Oxygen Hoods Labels	21/01/11

Comments on Labels:

Comments on Risks Labels:

no risks with labels

Documentation Updates / Changes

Comments on Document Changes:

files added to comply with new essencial requirements

Comments on Risks with Document Changes:

no risks with new documentation

Review of Issues

Number of Issues reviewed: 16

Issue ID	Subject
35477	Purchase Order POR08314
35240	Medical Technology - Accout 0007689
30332	Returned Items SOR478
28434	Eden Medical
28433	Eden Medical
27853	Stock availability
31715	no cop for pp8050
27927	Missing Hood
35183	Medical Technology - Meditech (account 00007689)
35182	Medical Technology - Meditech (account 00007689)
35181	Medical Technology - Meditech (account 00007689)
29716	POR07931 PP8509 Delivery date Change
29715	POR07931 PP8509 Delivery date Change
32910	75x PP8050 required
30389	Returned oxygen hood
32909	PP8050 Steve Hardaker Sales Forcasts

Comments on Issues:

no problems found in the issues

Comments on Risks with Issues:

no risks associated 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 :

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 :