



31/Jul/2013

Post market Surveillance and Risk Assessment Re-evaluation

Tube Holder
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 31 / 07 / 13

Stock References Reviewed

Stock Reference	Description
PP8526	Ventilator Tube Holder 14 Slots

Comments on Stock references review:

correct.

Supplier Information on Main and Component Parts

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
PP8526	Ventilator Tube Holder 14 Slots	00009022	Tanda Engineering Ltd	A

Comments on Suppliers:

Supplier ratings ok

Sales Information

Stock Reference	Description	2007	2008	2009	2010	2011	2012	2013
PP8526	Ventilator Tube Holder 14 Slots		0	1	6	2	0	6

Comments on Sales Information:

Still selling units. albeit in low numbers.

New Countries

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

Comments on Sales to Countries:

Only sell to U.K.

Comments on Risks with Sales to Countries:

no risks identified.

Returns Information

Stock Reference	Fault	2007	2008	2009	2010	2011	2012	2013
PP8526	Incorrect Hole sizes		2					

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 design changes

Comments on Risks with Design Changes:

no risks identified.

User Instructions

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
2050	Tube Holder Instructions for Use / User Manual	18/06/07

Comments on User Instructions:

No changes to instructions

Comments on Risks User Instructions:

n/a

Labels

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
9169	No accessory labels	18/10/11
7498	Head Box Oxygen Hoods Labels	21/01/11
2055	Tube Holder Labels	19/06/07

Comments on Labels:

Comments on Risks Labels:

no risks identified

Documentation Updates / Changes

Comments on Document Changes:

Added expected life document.

Comments on Risks with Document Changes:

no risks identified.

Review of Issues

Number of Issues reviewed: 1

Issue ID	Subject
39567	

Comments on Issues:

No problems found in the Issues system

Comments on Risks with Issues:

no risks identified

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 :

N/a for a tube holder

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 for regarding tube holders,