



VIA MED

Tube Holder

For use in holding ventilator, oxygen tubing, I.V. tubing and electronic transducer cables.

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

Carried out by Derek Lamb
13 / 06 / 18



VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
-  Countries Review
-  Returns Review
-  Design Changes Review
-  User Instructions Review
-  Labels Review
-  Document Updates Review
-  Internal Issues Review
-  Clinical / FDA Incidents online search

Stock References Review

Stock Reference	Description
PP8526	Ventilator Tube Holder 14 Slots
PP8561	Ventilator Tubing holder 2 Slots
PP8605	Ventilator Tubing Holder
PP8611	Ventilator Tubing Holder
PP8628A	Ventilator Tubing Holder
PP8643	Ventilator Tubing Holder
PP8644	Ventilator Tubing Holder
PP8647	Ventilator Tubing Holder
PP8691	Ventilator Tubing Holder
PP8706	Ventilator Tubing Holder
PP8708	Ventilator Tubing Holder
PP8716	Ventilator Tubing Holder 14 slots
PP8726	Ventilator Tubing Holder 8 Slots
PP8763	Ventilator Tubing Holder 10 Slots
PP8769	Ventilator Tubing Holder

Comments on Stock references review:

references upto date

product range has been discontinued

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
PP8526	Ventilator Tube Holder 1	00009022	PP8526	Tanda Engineering Ltd	B
PP8605	Ventilator Tubing Holder	00009022	PP8605	Tanda Engineering Ltd	B
PP8611	Ventilator Tubing Holder	00009022	PP8611	Tanda Engineering Ltd	B
PP8706	Ventilator Tubing Holder	00009022	PP8706	Tanda Engineering Ltd	B
PP8708	Ventilator Tubing Holder	00009022	PP8708	Tanda Engineering Ltd	B
PP8716	Ventilator Tubing Holder	00009022	PP8716	Tanda Engineering Ltd	B
PP8726	Ventilator Tubing Holder	00009022	PP8726	Tanda Engineering Ltd	B
PP8763	Ventilator Tubing Holder	00009022	PP8763	Tanda Engineering Ltd	B
PP8769	Ventilator Tubing Holder	00009022	PP8769	Tanda Engineering Ltd	B

Comments on Suppliers:

supplier upto date

Sales Information

Stock Reference	Description	2012	2013	2014	2015	2016	2017	2018
PP8526	Ventilator Tube Holder 1	0	6					
PP8561	Ventilator Tubing holder 2 Slots							
PP8605	Ventilator Tubing Holder							
PP8611	Ventilator Tubing Holder							
PP8628A	Ventilator Tubing Holder							
PP8643	Ventilator Tubing Holder							
PP8644	Ventilator Tubing Holder							
PP8647	Ventilator Tubing Holder							
PP8691	Ventilator Tubing Holder							
PP8706	Ventilator Tubing Holder							
PP8708	Ventilator Tubing Holder							
PP8716	Ventilator Tubing Holder	10	7	2	6	6	1	
PP8726	Ventilator Tubing Holder			2		2		
PP8763	Ventilator Tubing Holder							
PP8769	Ventilator Tubing Holder							

Comments on Sales Information:

product range has been discontinued

Countries Review

Country	2012	2013	2014	2015	2016	2017	2018
SC Scotland			[X]		[X]		
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	

Comments on Sales to Countries:

product range has been discontinued

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2012	2013	2014	2015	2016	2017	2018
PP8526	Incorrect Hole Sizes						6	
PP8526	Unchecked - Returned To Stock	10	1					

Comments on Returns:

product range has been discontinued

Comments on Risks with Returns and Potential Re-work:

no risks

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no design changes

Comments on Risks with Design Changes:

no risks

User Instructions Review

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 user instructions

Comments on Risks User Instructions:

no risks identified

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
2055	Tube Holder Labels	19/06/07

Comments on Labels:

no changes to labels

Comments on Risks Labels:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
23128	Tube Holder Risk analysis reports (2)	22/10/17
20174	Tube Holder Clinical Trials Reports Reviews and Post Market Surv...	17/05/17

Comments on Document Changes:

only risk reports updated
no document changes

Comments on Risks with Document Changes:

no risks

Internal Issues Review

Number of Issues reviewed: 5

Issue ID	Subject
100468	Office Meeting Sales Back Orders Review - By Customer Backorder 00001700 PP8716 ORD87754
100692	Office Meeting Back Order Report POR11387 PP8716 //
102125	Office Meeting Stock Processing PP8526
119578	Office Meeting Stock Processing PP8526 Listed on Ebay
66287	Office Meeting Product Feedback Negative PP8716

Comments on Issues:

very few issues, no complaints or non conformances found in the issue system

Comments on Risks with Issues:

no risks found in the issue system

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00001700 PP8716 ORD87754

Issue ID #100468

Date Created 10/Aug/2017

Issued To: General

Completed Status: 14 Sep 2017

Stock Ref: PP8716

Opera A/c: 00001700

Order Number: ORD87754

Notes:

10 Aug 2017 08:01:21 AM Catherine Spence
Back Order - Supplier

11 Aug 2017 09:18:02 AM Emily Hanson
emailed. lead time is around 6 week.

Issues:100468

- Back Order Report

POR11387 PP8716 //

Issue ID #100692

Date Created 14/Aug/2017

Issued To: Jonathan Connor

Completed Status: 14 Aug 2017

Notes:

POR11387 PP8716 Estimated ship to us date changed to / /

Issues:100692

VIAMED Stock Meeting - Stock Processing

PP8526

Issue ID #102125

Date Created 04/Sep/2017

Issued To: Jonathan Connor

Completed Status: 04 Sep 2017

Notes:

Added by Jonathan Connor sent to Jonathan Connor

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

PP8526 on hold - small holes - customers keep ordering and this is not the part they require. Usually need PP8716

03 May 2018 Catrin Hird

Created Related Issue #119578

Added by Catrin Hird sent to Catrin Hird

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

Listed on Ebay with exact measurements.

Issues:102125

VIAMED Stock Meeting - Stock Processing

PP8526 Listed on Ebay

Issue ID #119578

Date Created 03/May/2018

Issued To: Catrin Hird

Completed Status: 03 May 2018

Notes:

Added by Catrin Hird sent to Catrin Hird

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

Listed on Ebay with exact measurements.

Issues:119578

VIAMED Feedback - Product Feedback Negative

PP8716

Issue ID #66287

Date Created 08/Jan/2016

Issued To: Steve Nixon

Completed Status: 09 Aug 2017

Notes:

Added by Katie Evans sent to Katie Evans

Bart's Health called to enquire about the price, was told these are extremely expensive

08 Apr 2016 Katie Evans

08 Apr 2016 Katie Evans

Next Action Changed From Katie Evans To Steve Nixon

Issues:66287

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 :

no reports found

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 :

no reports found