

## **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 24 / 07 / 19



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## 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:

part numbers upto date

# Supplier Review

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

Comments on Suppliers:

supplier review upto date

# **Sales Information**

Stock Reference	Description	2013	2014	2015	2016	2017	2018	2019
PP8526	Ventilator Tube Holder 1	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	7	2	6	6	1		
PP8726	Ventilator Tubing Holder		2		2			
PP8763	Ventilator Tubing Holder							
PP8769	Ventilator Tubing Holder							

Comments on Sales Information:

no units sold since 2017,

## **Countries Review**

Country	2013	2014	2015	2016	2017	2018	2019
SC Scotland		[X]		[X]			
UK United Kingdom	[X]	[X]	[X]	[X]	[X]		

Comments on Sales to Countries:

only sold to the UK

Comments on Risks with Sales to Countries:

no new risks

#### Returns and Q.A. Fails Review

Stock Reference	Fault	2013	2014	2015	2016	2017	2018	2019
PP8526	Incorrect Hole Sizes					6		
PP8526	Unchecked - Returned To Stock	1						

Comments on Returns:

very limited number of failures ever,

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

### **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 instruction changes

Comments on Risks User Instructions:

### **Labels Review**

#### Showing Documents Filed in F7/F8 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 label changes

Comments on Risks Labels:

# Documentation Updates / Changes

Document ID	Description	Date Added/Updated
26425	Tube Holder Clinical Trials Reports Reviews and Post Market Surv	13/06/18

Comments on Document Changes:

only updated document was the PMS last year

Comments on Risks with Document Changes:

no

# Internal Issues Review Number of Issues reviewed: 1

Issue ID	Subject
134443	Office Meeting Price Lists UK Oxygen hood pricing incorrect in Intrastats

Comments on Issues:

only issue is a pricing query

Comments on Risks with Issues:

non

VIAMED Sales And Marketing - Price Lists UK

#### Oxygen hood pricing incorrect in Intrastats

Issue ID #134443

Date Created 17/Dec/2018

Issued To: Catrin Hird

Completed Status: 18 Dec 2018

#### Notes:

Added by Steve Hardaker sent to Catrin Hird

There seems to be an error on some of the Intrastats pricing for the acrylic items on the recent mailshot.

Milton Keynes Hospital got the mailing and enquired about PP8788 and PP8526. On both of these, the prices listed on Intrastats appears to be 25% off the price already discounted by 15% previously, instead of 25% off the List price.

I mentioned it to the office staff today but is this something you can correct or does it need Steve or Derek to fix?

18 Dec 2018 Catrin Hird
Updated, thanks for spotting. Will ask DL to push prices through now.

18 Dec 2018 Steve Hardaker

Issues:134443

#### 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 :

product stopped

#### 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:

product stopped