



VIA MED

Tube Holder

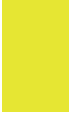

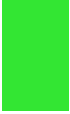









For use in holding ventilator, oxygen tubing, I.V. tubing and electronic transducer cables.

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

Carried out by Derek Lamb
20 / 04 / 16



VIA MED

-  Stock References Review
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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	A
PP8605	Ventilator Tubing Holder	00009022	PP8605	Tanda Engineering Ltd	A
PP8611	Ventilator Tubing Holder	00009022	PP8611	Tanda Engineering Ltd	A
PP8706	Ventilator Tubing Holder	00009022	PP8706	Tanda Engineering Ltd	A
PP8708	Ventilator Tubing Holder	00009022	PP8708	Tanda Engineering Ltd	A
PP8716	Ventilator Tubing Holder	00009022	PP8716	Tanda Engineering Ltd	A
PP8726	Ventilator Tubing Holder	00009022	PP8726	Tanda Engineering Ltd	A
PP8763	Ventilator Tubing Holder	00009022	PP8763	Tanda Engineering Ltd	A
PP8769	Ventilator Tubing Holder	00009022	PP8769	Tanda Engineering Ltd	A

Comments on Suppliers:

supplier review upto date

Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
PP8526	Ventilator Tube Holder 1	12	2	0	12			
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			20	14	4	12	8
PP8726	Ventilator Tubing Holder	1				4		4
PP8763	Ventilator Tubing Holder							
PP8769	Ventilator Tubing Holder							

Comments on Sales Information:

Still selling in low numbers

Countries Review

Country	2010	2011	2012	2013	2014	2015	2016
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

no new countries

Comments on Risks with Sales to Countries:

no risks with countries

Returns Review

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
PP8526	Incorrect Hole sizes							
PP8526	Unchecked - Returned to Stock							

Comments on Returns:

no returns

Comments on Risks with Returns and Potential Re-work:

n/a no returns

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no design changes

Comments on Risks with Design Changes:

n/a no design changes

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 the ifu

Comments on Risks User Instructions:

no risk identified with the ifu

Labels Review

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:

Labels in the file are coming up blank,
Issue created 70251 to see why

Comments on Risks Labels:

See issue 70251

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
15430	Tube Holder Risk analysis reports (2)	11/08/15
15183	No risks disposal	21/07/15
14855	Tube Holder Clinical Trials Reports Reviews and Post Market Surv...	17/03/15

Comments on Document Changes:

no comments

Comments on Risks with Document Changes:

no risks identified

Internal Issues Review

Number of Issues reviewed: 5

Issue ID	Subject
67728	Backorder 00001480 PP8726 ORD78805
66399	Backorder 00003095 PP8716 ORD78069
15153	Can this be completed/closed?
66287	PP8716
67615	PP8726 Price Standard Web Price Pounds request Large Quantity

Comments on Issues:

just price enquirys and orders

Comments on Risks with Issues:

no risks in the issues system

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 :

not a medical product as such, no clinical data available

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 :

not a medical product as such, no fda reports