

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 16 / 09 / 20



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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 correct, Product discontinued in 2017

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:

Product discontinued in 2017 no longer need to review Tanda, it should drop off the approved suppliers in next 18 Months

Sales Information

Stock Reference	Description	2014	2015	2016	2017	2018	2019	2020
PP8526	Ventilator Tube Holder 1							
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	2	6	6	1			
PP8726	Ventilator Tubing Holder	2		2				
PP8763	Ventilator Tubing Holder							
PP8769	Ventilator Tubing Holder							

Comments on Sales Information:

Countries Review

Comments on Sales to Countries:

Product discontinued in 2017

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2014	2015	2016	2017	2018	2019	2020
PP8526	Incorrect Hole Sizes				6			
PP8526	Unchecked - Returned To Stock							

Comments on Returns:

Product discontinued in 2017

Comments on Risks with Returns and Potential Re-work:

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

Product discontinued in 2017

Comments on Risks with 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:

Product discontinued in 2017

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:

Product discontinued in 2017

Comments on Risks Labels:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
30402	Tube Holder Clinical Trials Reports Reviews and Post Market Surv	24/07/19

Comments on Document Changes:

Product discontinued in 2017

Comments on Risks with Document Changes:

Clinical / FDA Incidents online search

Comments on Issue Inical Investigation online review

Product discontinued in 2017

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem : Do any of the Results indicate outdated Technology : Comments on Clinical Search :