



# VIA MED

## T Adaptors

Class IIa  
Via Rule Rule 9  
Assesment Route Annex II  
NBOG MD 0101

Carried out by Derek Lamb  
17 / 05 / 17



# VIA MED

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# Stock References Review

Stock Reference	Description
0120090	Oxygen sensor O ring.
0120098	Oxygen sensor flow diverter O ring 15mm
0120099	Oxygen sensor flow diverter 15mm.
0120100	`T` adapter. 22mm I.D. - 22mm O.D.
0120103	`T` adapter: 15mm paediatric circuits
0120106	`T` adapter. 22mm I.D. - 22mm O.D.
0120108	`T` adapter. 22mm O.D. - 22mm O.D.
0120109	`T` adapter non rebreathing.
0120110	Perfusion Circuit `T` Adapter.
0120121	FlowCheck
0120125	Connector: 22mm I.D. - 22mm I.D.
0120126	Connector 15mm I.D./22mm O.D.-22mm O.D.
0120127	Connector: 15mm I.D./22mm O.D. - 6.5mm
0120128	Connector - 15mm I.D. - 22mm I.D.
0120129	Connector - 22mm O.D - 30mm O.D.
0120130	Connector 15mm O.D. - tapered barbed
0120131	Connector 15mm I.D./22mm O.D. - tapered
0120133	Connector 22mm I.D./30mm O.D. - tapered
0120139	Adapter 15mm I.D. - 10mm I.D
0120140	Adapter 15mm I.D. - 15mm I.D
0120141	Adapter 15mm I.D./22mm O.D. -
0120142	Adapter 15mm I.D./22mm O.D. -
0120149	Adapter 15mm I.D. - 10mm I.D
0120150	Adapter 15mm I.D. - 15mm I.D
0120151	Adapter 15mm I.D./22mm O.D. -
0120152	Adapter 15mm I.D. - 15mm I.D
0120153	Adapter 15mm I.D./22mm O.D. -
0120159	Adapter 15mm I.D. - 10mm I.D
0120160	FiO2 sensor adapter.
0120161	FiO2 activator for small bore tubing.
0120162	FiO2 activator for 15mm O2 sensors
0120163	FiO2 activator for 18mm O2 sensors
0120164	Spring loaded FiO2 sensor adapter.
0120165	Replacement `T` assembly for MT 100.
0120166	Replacement activator for MT 100.
0120200	Adult MDI Adapter.
0120201	Adult MDI Adapter.
0120202	Adult MDI Adapter.
0120203	Adult MDI Adapter.
0120204	Paediatric MDI Adapter.
0120205	Paediatric MDI Adapter.
0120206	MDI Adapter - Replacement Rubber Cap.

Stock Reference	Description
0120207	MDI Adapter.
0120208	MDI Adapter.
0120300	Wye Connector
0120301	Wye Connector with pressure port.
0120302	Wye Connector with temperature probe
0120303	Wye Connector with temperature probe
0120304	Temperature probe port cap.
0120305	Wye connector 60 degrees.
0120306	Wye connector 90 degrees.
0120307	Wye connector 60 degrees.
0120310	Auto PEEP measurement device.
0120400	`T` adapter. 22mm I.D. - 22mm O.D.
0120401	`T` adapter. 22mm I.D. - 22mm O.D.
0120402	`T` adapter. 22mm I.D. - 22mm O.D.

Comments on Stock references review:

all T adaptor part numbers upto date

# Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0120121	FlowCheck	00011712	R217P18	Maxtec Inc.	B
0120100	`T` adapter. 22mm I.D. -	00011844	BE 125-1TD	Instrumentation Industri	A
0120106	`T` adapter. 22mm I.D. -	00011844	BE 117-W PK 10	Instrumentation Industri	A
0120108	`T` adapter. 22mm O.D. -	00011844	BE 125-1	Instrumentation Industri	A
0120109	`T` adapter non rebreat	00011844	BE 117 PK10	Instrumentation Industri	A
0120130	Connector 15mm O.D. - t	00011844	BE 145-2P PK 50	Instrumentation Industri	A
0120131	Connector 15mm I.D./22m	00011844	BE 145-1522P 50	Instrumentation Industri	A
0120133	Connector 22mm I.D./30m	00011844	BE 145-2230P 50	Instrumentation Industri	A
0120139	Adapter 15mm I.D. - 10m	00011844	PF 1510 PACK 50	Instrumentation Industri	A
0120140	Adapter 15mm I.D. - 15m	00011844	PF 1515	Instrumentation Industri	A
0120141	Adapter 15mm I.D./22mm	00011844	KC 2124	Instrumentation Industri	A
0120152	Adapter 15mm I.D. - 15m	00011844	PF 1515 PACK 50	Instrumentation Industri	A
0120153	Adapter 15mm I.D./22mm	00011844	KC 2124 PK 100	Instrumentation Industri	A
0120161	FiO2 activator for small	00011844	BE 101-3A	Instrumentation Industri	A
0120162	FiO2 activator for 15mm	00011844	ACT 15/22	Instrumentation Industri	A
0120163	FiO2 activator for 18mm	00011844	ACT 18/22	Instrumentation Industri	A
0120164	Spring loaded FiO2 senso	00011844	MT100	Instrumentation Industri	A
0120165	Replacement `T` assembly	00011844	MT100-TA	Instrumentation Industri	A
0120166	Replacement activator fo	00011844	MT100-A	Instrumentation Industri	A
0120201	Adult MDI Adapter.	00011844	RTC 22-D	Instrumentation Industri	A
0120203	Adult MDI Adapter.	00011844	RTC 23-D	Instrumentation Industri	A
0120204	Paediatric MDI Adapter.	00011844	RTC 15-D	Instrumentation Industri	A
0120205	Paediatric MDI Adapter.	00011844	RTC 15-P	Instrumentation Industri	A
0120208	MDI Adapter.	00011844	RTC 21-D PK 50	Instrumentation Industri	A
0120402	`T` adapter. 22mm I.D. -	00011844	BE 125-1TD PK100	Instrumentation Industri	A

Comments on Suppliers:

Supplier review upto date

# Sales Information

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
0120090	Oxygen sensor O ring.	60	20	20	11	10		
0120098	Oxygen sensor flow diverter O ring 15mm		92	50	6	30	30	
0120099	Oxygen sensor flow diverter 15mm.	161	86	110	70	30	61	7
0120100	`T` adapter. 22mm I.D. -	3858	2168	1368	974	1080	434	96
0120103	`T` adapter: 15mm paediatric circuits	46	79	23	42	196	359	8
0120106	`T` adapter. 22mm I.D. -	12				20	57	
0120108	`T` adapter. 22mm O.D. -				4		1	
0120109	`T` adapter non rebreat						10	20
0120110	Perfusion Circuit `T` Adapter.			1		1	18	1
0120121	FlowCheck						3	
0120125	Connector: 22mm I.D. - 22mm I.D.	45		14	32	3	16	
0120126	Connector 15mm I.D./22mm O.D.-22mm O.D.	-26	145	21	57	7	8	
0120127	Connector: 15mm I.D./22mm O.D. - 6.5mm	14			24	2	12	
0120128	Connector - 15mm I.D. - 22mm I.D.					3	8	
0120129	Connector - 22mm O.D - 30mm O.D.					3	3	
0120130	Connector 15mm O.D. - t	35		1	37	182	157	8
0120131	Connector 15mm I.D./22m	203	36	224	122	192	306	9
0120133	Connector 22mm I.D./30m	58	48	34	62	30	75	2
0120139	Adapter 15mm I.D. - 10m	3	31	7	23	25	20	
0120140	Adapter 15mm I.D. - 15m	28	38	120	57	149	90	
0120141	Adapter 15mm I.D./22mm	1598	1007	280	92	124	157	
0120142	Adapter 15mm I.D./22mm O.D. -							
0120149	Adapter 15mm I.D. - 10mm I.D							
0120150	Adapter 15mm I.D. - 15mm I.D	10			10	12		
0120151	Adapter 15mm I.D./22mm O.D. -	1	3	1	1		3	
0120152	Adapter 15mm I.D. - 15m							
0120153	Adapter 15mm I.D./22mm		26	1	6		2	
0120159	Adapter 15mm I.D. - 10mm I.D						1	
0120160	FiO2 sensor adapter.	9						
0120161	FiO2 activator for small							
0120162	FiO2 activator for 15mm							
0120163	FiO2 activator for 18mm							
0120164	Spring loaded FiO2 senso							
0120165	Replacement `T` assembly						3	
0120166	Replacement activator fo							
0120200	Adult MDI Adapter.						1	
0120201	Adult MDI Adapter.	500					1	
0120202	Adult MDI Adapter.						1	
0120203	Adult MDI Adapter.						1	
0120204	Paediatric MDI Adapter.							
0120205	Paediatric MDI Adapter.							
0120206	MDI Adapter - Replacement Rubber Cap.							

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
0120207	MDI Adapter.							
0120208	MDI Adapter.				20			
0120300	Wye Connector							
0120301	Wye Connector with pressure port.							
0120302	Wye Connector with temperature probe							
0120303	Wye Connector with temperature probe							
0120304	Temperature probe port cap.							
0120305	Wye connector 60 degrees.							
0120306	Wye connector 90 degrees.							
0120307	Wye connector 60 degrees.							
0120310	Auto PEEP measurement device.							
0120400	`T` adapter. 22mm I.D. - 22mm O.D.				1	1	1	1
0120401	`T` adapter. 22mm I.D. - 22mm O.D.					4	1	1
0120402	`T` adapter. 22mm I.D. -			1		4		

Comments on Sales Information:

limited number of sales

# Countries Review

Country	2011	2012	2013	2014	2015	2016	2017
AU Austria				[X]			
B Belgium	[X]			[X]			
BA State of Bahrain					[X]		
C China					[X]		
CZ Czech Republic	[X]			[X]			
DE Denmark	[X]	[X]	[X]		[X]	[X]	
EG Egypt		[X]					
F France	[X]	[X]	[X]	[X]	[X]	[X]	
FI Finland	[X]	[X]		[X]	[X]	[X]	
G Germany	[X]	[X]	[X]	[X]	[X]	[X]	[X]
GR Greece							
HK Hong Kong	[X]						
IN India		[X]	[X]				
IRE Ireland	[X]	[X]	[X]	[X]	[X]		
IT Italy				[X]	[X]	[X]	
J Japan	[X]	[X]			[X]	[X]	
K South Korea							
KU Kuwait							
LEB Lebanon							
MA Malaysia							
NE Netherlands	[X]						
NO Norway							
OM Oman	[X]						
P Poland					[X]	[X]	
PO Portugal	[X]						
RO Romania					[X]	[X]	
RU Russia	[X]	[X]	[X]	[X]		[X]	
SER Serbia	[X]						
SI Singapore							
SRI Sri Lanka			[X]				
SW Sweden	[X]		[X]	[X]	[X]	[X]	[X]
SWI Switzerland			[X]		[X]		
TT Trinidad and Tobago			[X]				
UAE U A E					[X]		
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

sales from various countries but in low numbers

Comments on Risks with Sales to Countries:

no risks with any countries



# Returns and Q.A. Fails Review

Stock Reference	Fault	2011	2012	2013	2014	2015	2016	2017
0120100	No Fault Return to Stock						1	
0120100	Unchecked - Returned to Stock	12						
0120106	New							
0120108	Unchecked - Returned to Stock				9			
0120126	No Fault Return to Stock	24						
0120131	Unchecked - Returned to Stock							

## Comments on Returns:

very small number of returns  
all all no fault found

## Comments on Risks with Returns and Potential Re-work:

no issues with returned stock

# 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

# User Instructions Review

## Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
15718	T Adaptors Instructions for Use User Manual BE-117	22/09/15
15717	T Adaptors Instructions for Use User Manual RTC-21-A	22/09/15
15716	T Adaptors Instructions for Use User Manual RTC-15-D	22/09/15
15710	T Adaptors Instructions for Use User Manual III Instructions f...	22/09/15
8947	T Adaptors Instructions for Use / User Manual Tapers	18/10/11
729	T Adaptors Instructions for Use / User Manual BE 117 Non Rebreat...	25/09/06

Comments on User Instructions:

no changes to ifu

Comments on Risks User Instructions:

no risks with ifu

# Labels Review

## Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
15715	T Adaptors Labels T Label warning	22/09/15
9169	No accessory labels	18/10/11
7689	T Adaptors Labels	15/02/11

Comments on Labels:

no changes to labels

do we still use the warning lables

Comments on Risks Labels:

highlights fitting plastic and metal t together

# Documentation Updates / Changes

Document ID	Description	Date Added/Updated
17428	Viamed CE Certificate CE01389	07/09/16
17176	T Adaptors User Feedback 0120141	11/07/16
17101	Instrumentation Industries Inc - ISO13485	27/06/16
16788	T Adaptors Clinical Trials Reports Reviews and Post Market Surve...	20/04/16

Comments on Document Changes:

User feed back positive,  
and states is fit for purpose

Comments on Risks with Document Changes:

no risks with documents

# Internal Issues Review

Number of Issues reviewed: 49

ID	Subject
9	0120121 FlowCheck Adapter - Marketing Schedule
3	Backorder 00000029 0120100 ORD84195
8	Backorder 00000030 0120099 ORD82093
6	Backorder 00000200 0120140 ORD79968
3	Backorder 00000680 0120100 ORD84173
5	Backorder 00000680 0120100 ORD84769
7	Backorder 00001002 0120140 ORD84018
2	Backorder 00001601 0120100 ORD82187
5	Backorder 00001601 0120100 ORD84883
4	Backorder 00001830 0120125 ORD80081
8	Backorder 00001830 0120126 ORD80081
2	Backorder 00001910 0120100 ORD81479
2	Backorder 00003400 0120401 ORD83114
0	Backorder 00003640 0111235 ORD81223
2	Backorder 00003640 0120110 ORD80038
6	Backorder 00003640 0120121 ORD81223
2	Backorder 00005101 0120401 ORD85826
3	Backorder 00005363 0120110 ORD81358
5	Backorder 00005445 0120100 ORD86146
7	Backorder 00006424 0120109 ORD85878
2	Backorder 00007475 0120103 ORD83272
6	Backorder 00007696 0120100 ORD82701
0	Backorder 00011755 0120400 ORD85396
3	Backorder 00012148 0120131 ORD84574
4	Extended Desriptions
7	Manchester Royal - MX300s
4	Maxtec O-rings degrading in anaesthetic applications
4	POR10739 0120121 //
6	POR10739 0120121 //
4	POR10830 0120121 //
0	POR10830 0120121 //
1	POR10830 0120121 //
9	POR10984 0120131 //
0	POR10984 0120133 //
1	POR10984 0120402 //
5	POR11217 0120152 //
2	POR11217 0120152 //
6	POR11217 0120153 //
3	POR11217 0120153 //
1	POR11252 0120109 //
8	POR11252 0120109 //
2	POR11252 0120402 //

ID	Subject
1	Price List Oxygen Monitoring Catalogue
0	Price List Oxygen Monitoring Catalogue
8	Request Scanning Item to Sale or return
9	Request Scanning Item to Sale or return
0	Request Scanning Item to Sale or return
9	Returned Items SOR737
9	Send item on Sale Or Return MX300 on SOR737 to Manchester Royal Infirmary Obtain purchase order or arrange return of goods

Comments on Issues:

o ring issue with another product has been highlighted during search on T pieces, looks like the problem has been solved by replacing the orings

Comments on Risks with Issues:

no risks found in the issues relating to the T pieces

# 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 :

Its a Simple T piece, T Connectors.  
no clinical reports available for such a simple component.

## 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 fda reports available for such a simple component.