



VIA MED

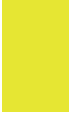
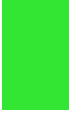
T Adaptors

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

Carried out by Derek Lamb
20 / 04 / 16



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:

part numbers upto date

Supplier Review

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

Comments on Suppliers:

supplier review upto date

Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
0120090	Oxygen sensor O ring.		40	20	20	11	10	
0120098	Oxygen sensor flow diverter O ring 15mm			92	50	6	30	30
0120099	Oxygen sensor flow diverter 15mm.	330	121	86	110	70	30	32
0120100	`T` adapter. 22mm I.D. -	2512	2889	2168	1368	974	1080	113
0120103	`T` adapter: 15mm paediatric circuits	52	39	79	23	42	196	322
0120106	`T` adapter. 22mm I.D. -		8				20	57
0120108	`T` adapter. 22mm O.D. -	3				4		1
0120109	`T` adapter non rebreathing.							10
0120110	Perfusion Circuit `T` Adapter.				1		1	3
0120121	FlowCheck							
0120125	Connector: 22mm I.D. - 22mm I.D.	2	30		14	32	3	3
0120126	Connector 15mm I.D./22mm O.D.-22mm O.D.	41	-9	145	21	57	7	
0120127	Connector: 15mm I.D./22mm O.D. - 6.5mm		10			24	2	4
0120128	Connector - 15mm I.D. - 22mm I.D.						3	
0120129	Connector - 22mm O.D - 30mm O.D.	4					3	
0120130	Connector 15mm O.D. - t	10	25		1	37	182	130
0120131	Connector 15mm I.D./22m	88	139	36	224	122	192	260
0120133	Connector 22mm I.D./30m	93	42	48	34	62	30	42
0120139	Adapter 15mm I.D. - 10m		3	31	7	23	25	10
0120140	Adapter 15mm I.D. - 15m	41	27	38	120	57	149	22
0120141	Adapter 15mm I.D./22mm	620	1554	1007	280	92	124	107
0120142	Adapter 15mm I.D./22mm O.D. -							
0120149	Adapter 15mm I.D. - 10mm I.D	1						
0120150	Adapter 15mm I.D. - 15mm I.D		9			10	12	
0120151	Adapter 15mm I.D./22mm O.D. -	3	1	3	1	1		
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.		6					
0120161	FiO2 activator for small							
0120162	FiO2 activator for 15mm							
0120163	FiO2 activator for 18mm							
0120164	Spring loaded FiO2 senso	4						
0120165	Replacement `T` assembly	8						3
0120166	Replacement activator fo							
0120200	Adult MDI Adapter.							
0120201	Adult MDI Adapter.	400	500					
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	2010	2011	2012	2013	2014	2015	2016
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
0120401	`T` adapter. 22mm I.D. - 22mm O.D.						4	
0120402	`T` adapter. 22mm I.D. -				1		4	

Comments on Sales Information:

units still selling

Countries Review

Country	2010	2011	2012	2013	2014	2015	2016
AU Austria					[X]		
B Belgium	[X]	[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]	[X]
FI Finland	[X]	[X]	[X]		[X]	[X]	
G Germany	[X]	[X]	[X]	[X]	[X]	[X]	[X]
GR Greece	[X]						
HK Hong Kong		[X]					
IN India			[X]	[X]			
IRE Ireland	[X]	[X]	[X]	[X]	[X]	[X]	
IT Italy	[X]				[X]	[X]	[X]
J Japan	[X]	[X]	[X]			[X]	
K Korea							
KU Kuwait							
LEB Lebanon							
MA Malaysia							
NE Netherlands		[X]					
NO Norway	[X]						
OM Oman		[X]					
P Poland						[X]	[X]
PO Portugal		[X]					
RO Romania	[X]					[X]	
RU Russia	[X]	[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:

BA State of Bahrain,C China
new countries

Comments on Risks with Sales to Countries:

no risks with new countries

Returns Review

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
0120100	Unchecked - Returned to Stock							
0120108	Unchecked - Returned to Stock							
0120126	No Fault Return to Stock							
0120131	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
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:

Still fit for purpose

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:

labels still fit for purpose

Comments on Risks Labels:

no risks with labels

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
15720	T Adaptors Software software	22/09/15
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
15715	T Adaptors Labels T Label warning	22/09/15
15714	T Adaptors Risk analysis certificate Certificate	22/09/15
15713	T Adaptors EC Declaration of Conformance Reuseable	22/09/15
15712	T Adaptors EC Declaration of Conformance single patient	22/09/15
15711	T Adaptors Specifications of Materials Tapers	22/09/15
15710	T Adaptors Instructions for Use User Manual III Instructions f...	22/09/15
15709	T Adaptors Cleaning Instructions III cleaning instructions	22/09/15
15428	T Adaptors Risk analysis reports	11/08/15
15418	PPE Equipment	11/08/15
15183	No risks disposal	21/07/15
14449	T Adaptors Drawings TTC 25-C DHR	07/10/14
14448	T Adaptors Packaging Trials and validation RTC25 Validation	07/10/14
14192	T Adaptors Clinical Trials Reports Reviews and Post Market Surve...	26/08/14

Comments on Document Changes:

files updated but actual documents old version

Comments on Risks with Document Changes:

no risks with new documents

Internal Issues Review

Number of Issues reviewed: 74

Issue ID	Subject
12275	
9630	
53287	0120151 required
56021	Backorder 00000029 0120100 ORD72349
56194	Backorder 00000029 0120100 ORD72436
63605	Backorder 00000029 0120100 ORD76488
68410	Backorder 00000109 0120159 ORD79122
69082	Backorder 00000170 0120140 ORD79433
55357	Backorder 00000550 0120100 ORD71945
61193	Backorder 00000550 0120100 ORD75337
62468	Backorder 00000550 0120100 ORD75937
60699	Backorder 00000580 0120100 ORD75121
57083	Backorder 00000590 0120140 ORD72963
63890	Backorder 00000590 0120401 ORD76696
55121	Backorder 00000680 0120100 ORD71795
55937	Backorder 00000680 0120100 ORD72300
57906	Backorder 00000680 0120100 ORD73465
68594	Backorder 00000680 0120100 ORD79211
67200	Backorder 00000990 0120400 ORD78558
59960	Backorder 00001466 0120140 ORD74746
55383	Backorder 00001480 0120100 ORD71975
67944	Backorder 00001601 0120100 ORD78913
65466	Backorder 00001640 0120100 ORD77544
65786	Backorder 00001853 0120127 ORD77749
58172	Backorder 00001870 0120090 ORD73640
61991	Backorder 00001910 0120140 ORD75657
66698	Backorder 00002040 0120103 ORD78242
59965	Backorder 00002600 0120140 ORD74758
63615	Backorder 00003970 0120110 ORD76493
62695	Backorder 00003970 0120150 ORD76034
66954	Backorder 00004210 0120100 ORD78453
67060	Backorder 00004210 0120110 ORD78453
67061	Backorder 00004210 0120165 ORD78453
57465	Backorder 00004400 0120139 ORD73258
60580	Backorder 00005260 0120150 ORD75034
62921	Backorder 00005260 0120150 ORD76114
66397	Backorder 00005445 0120099 ORD78058
66645	Backorder 00005445 0120099 ORD78212
66890	Backorder 00006777 0120140 ORD78403
66390	Backorder 00007273 0120153 ORD78072
56806	Backorder 00007314 0120100 ORD72759
54534	Backorder 00007475 0120103 ORD71396

Issue ID	Subject
69746	Backorder 00007475 0120103 ORD79691
65145	Backorder 00007586 0120100 ORD77324
63026	Backorder 00007598 0120106 ORD75918
64760	Backorder 00012117 0120100 ORD77094
66862	Backorder 00012148 0120106 ORD78401
64127	Backorder 00012746 0120141 ORD76835
68746	Backorder 00012746 0120141 ORD79224
58852	Backorder 00012774 0120140 ORD74086
67639	Backorder 00012942 0120109 ORD78800
68711	Backorder 00012956 0120103 ORD79238
57910	Discontinued by Supplier: 0120160 0120161 0120162 0120163
65847	Document/Picture (DOCID16110) Update Request
69243	FDA numbers for Instrumentation Industries Inc products
58073	GHX Brand
57401	GHX Brands
63023	Intersurgical connectors for technical files
51718	Leaflet - Maxtec Oxygen Monitors
55183	Leaflet Leaflet Maxtec Oxygen Monitors 3rd Checking Stage
57805	Leaflet Oxygen Monitoring Booklet Leaflet Designed
53707	Marketing Schedule Maxtec Flowcheck Datasheet to L and Intrastats
57099	Marketing Schedule Maxtec Flowcheck Inform staff of release and provide key points
57108	Maxtec Flowcheck
57107	Maxtec Flowcheck
57106	Maxtec Flowcheck
57105	Maxtec Flowcheck
57104	Maxtec Flowcheck
57103	Maxtec Flowcheck
57102	Maxtec Flowcheck
57101	Maxtec Flowcheck
57100	Maxtec Flowcheck
54505	Part Number 0120400
60100	Vandagraph - Stock Required

Comments on Issues:

mainly orders and stock issues,
no problems identified in the issues system

Comments on Risks with Issues:

no risk identified in the issue 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 :

Its a basic T piece, no clinical data required

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 :

Its a basic T piece, no fda results found