



VIA MED

## T Adaptors

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

Carried out by Derek Lamb  
24 / 07 / 19



# VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
-  Countries Review
-  Returns Review
-  Design Changes Review
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-  Document Updates Review
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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 number upto date

# Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0120099	Oxygen Sensor Flow Diver	00009190	9711002	Vandagraph	B
0120121	FlowCheck	00011712	R217P18	Maxtec Inc.	A
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
0120109	`T` adapter non rebreat	00011844	BE 117 PK10	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
0120159	Adapter 15mm I.D. - 10m	00011844	PF 1510 PACK 50	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
0120103	`T` adapter: 15mm paedia	00070006	0120103		Needs Grading
0120130	Connector 15mm O.D. - t	00070006	BE 145-2P PK 50		Needs Grading
0120131	Connector 15mm I.D./22m	00070006	BE 145-1522P 50		Needs Grading
0120133	Connector 22mm I.D./30m	00070006	BE 145-2230P 50		Needs Grading

Comments on Suppliers:

supplier reviews upto date for these products

# Sales Information

Stock Reference	Description	2013	2014	2015	2016	2017	2018	2019
0120090	Oxygen sensor O ring.	20	11	10				
0120098	Oxygen sensor flow diverter O ring 15mm	50	6	30	30	30		
0120099	Oxygen Sensor Flow Diver	110	70	30	61	29	7011	16
0120100	`T` adapter. 22mm I.D. -	1368	974	1080	434	259	222	77
0120103	`T` adapter: 15mm paedia	23	38	196	359	109	126	86
0120106	`T` adapter. 22mm I.D. -			20	57		108	
0120108	`T` adapter. 22mm O.D. -		4		1			
0120109	`T` adapter non rebreat				10	20	3	
0120110	Perfusion Circuit `T` Adapter.	1		1	18	6	4	3
0120121	FlowCheck				3			1
0120125	Connector: 22mm I.D. - 22mm I.D.	14	32	3	16	4	2	13
0120126	Connector 15mm I.D./22mm O.D.-22mm O.D.	21	57	7	8	3		10
0120127	Connector: 15mm I.D./22mm O.D. - 6.5mm		24	2	12	5	8	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	1	37	182	157	65	-8	80
0120131	Connector 15mm I.D./22m	224	122	192	306	56	38	90
0120133	Connector 22mm I.D./30m	34	62	29	75	22	37	10
0120139	Adapter 15mm I.D. - 10m	7	23	25	20		7	
0120140	Adapter 15mm I.D. - 15m	120	57	149	90	35	92	
0120141	Adapter 15mm I.D./22mm	280	92	124	157	50	49	3
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	12		1	2	1
0120151	Adapter 15mm I.D./22mm O.D. -	1	1		3	10	5	9
0120152	Adapter 15mm I.D. - 15m							
0120153	Adapter 15mm I.D./22mm	1	6		2	2	6	2
0120159	Adapter 15mm I.D. - 10m				1			
0120160	FiO2 sensor adapter.							
0120161	FiO2 activator for small							
0120162	FiO2 activator for 15mm							
0120163	FiO2 activator for 18mm							
0120164	Spring loaded FiO2 senso						2	1
0120165	Replacement `T` assembly				3			
0120166	Replacement activator fo							
0120200	Adult MDI Adapter.				1			
0120201	Adult MDI Adapter.				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	2013	2014	2015	2016	2017	2018	2019
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	2	3	2
0120401	`T` adapter. 22mm I.D. - 22mm O.D.			4	1	1		1
0120402	`T` adapter. 22mm I.D. -	1		4		3		

Comments on Sales Information:

units were selling in limited numbers

# Countries Review

Country	2013	2014	2015	2016	2017	2018	2019
AU Austria		[X]					
B Belgium		[X]					
BA Kingdom of Bahrain			[X]				
C China			[X]				
CHA Channel Islands						[X]	
CZ Czech Republic		[X]					
DE Denmark	[X]		[X]	[X]			
EG Egypt							
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							
HK Hong Kong							
IN India	[X]						
IRE Ireland	[X]	[X]	[X]				[X]
IT Italy		[X]	[X]	[X]		[X]	
J Japan			[X]	[X]			
K South Korea							
KU Kuwait							
LEB Lebanon							
MA Malaysia							[X]
NE Netherlands							
NI Northern Ireland							[X]
NO Norway						[X]	
OM Oman							
P Poland			[X]	[X]		[X]	
PO Portugal							[X]
RO Romania			[X]	[X]			
RU Russia	[X]	[X]		[X]	[X]	[X]	[X]
SA South Africa					[X]	[X]	
SC Scotland	[X]	[X]	[X]	[X]	[X]	[X]	[X]
SER Serbia							
SI Singapore							
SRI Sri Lanka	[X]						
SW Sweden	[X]	[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:

worldwide sales.



New country in 2018 CHA Channel Islands

Comments on Risks with Sales to Countries:

no

# Returns and Q.A. Fails Review

Stock Reference	Fault	2013	2014	2015	2016	2017	2018	2019
0120100	No Fault Return To Stock				1			
0120100	Unchecked - Returned To Stock							
0120106	New							
0120108	Unchecked - Returned To Stock		9					
0120126	No Fault Return To Stock							
0120130	No Fault Found						15	
0120131	Unchecked - Returned To Stock							

Comments on Returns:

Zero - Fault returns... Ever

Comments on Risks with Returns and Potential Re-work:

no, no reqork possible its a plastic T Piece

# Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no changes

Comments on Risks with Design Changes:

# User Instructions Review

## Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
30394	Instrumentation Industries - Sterilization and Disinfection Rec...	24/07/19
22626	T Adaptors Instructions for Use User Manual T Adapter User inf...	14/10/17
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:

added cleaning recommendations  
no other updates

Comments on Risks User Instructions:

# 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 change of labels

Comments on Risks Labels:

# Documentation Updates / Changes

Document ID	Description	Date Added/Updated
30396	Sterilization & Disinfection Recommendations	24/07/19
30394	Instrumentation Industries - Sterilization and Disinfection Rec...	24/07/19
29753	Viamed CE Certificate CE01389 Internal Use Only Cancellation Le...	29/05/19
28915	Instrumentation Industries Inc - ISO13485	13/03/19
27614	Instrumentation Industries Inc. Datasheet PF 1510	01/10/18
27612	Instrumentation Industries Inc. Datasheet PF 1515	01/10/18
27602	Instrumentation Industries Inc. California Proposition 65 Statem...	28/09/18
27600	Instrumentation Industries Inc. Packaging Symbols	28/09/18
27417	Essential requirements Generic File locator Generic CE File Atta...	16/09/18
26423	T Adaptors Clinical Trials Reports Reviews and Post Market Surve...	13/06/18

Comments on Document Changes:

added datasheets

Comments on Risks with Document Changes:

none

# Internal Issues Review

Number of Issues reviewed: 37

Issue ID	Subject
126756	Office Meeting Non Conformance Issues 0111211 Oxygen analyser w/o alarms - GB300.
127945	Office Meeting Sales Back Orders Review - By Customer Backorder 00000030 0120099 ORD94041
130099	Office Meeting Sales Back Orders Review - By Customer Backorder 00000109 0120106 ORD94533
139041	Office Meeting Sales Back Orders Review - By Customer Backorder 00000126 0120127 ORD96704
147943	Office Meeting Sales Back Orders Review - By Customer Backorder 00001995 0120151 ORD98688
131340	Office Meeting Sales Back Orders Review - By Customer Backorder 00002600 0120100 ORD94889
123251	Office Meeting Sales Back Orders Review - By Customer Backorder 00004825 0120140 ORD92876
149117	Office Meeting Sales Back Orders Review - By Customer Backorder 00006022 0120126 ORD98937
146025	Office Meeting Sales Back Orders Review - By Customer Backorder 00006570 0120110 ORD98253
133177	Office Meeting Sales Back Orders Review - By Customer Backorder 00006777 0120139 ORD95356
127831	Office Meeting Sales Back Orders Review - By Customer Backorder 00007273 0120153 ORD93731
130759	Office Meeting Sales Back Orders Review - By Customer Backorder 00007291 0120140 ORD94674
128318	Office Meeting Sales Back Orders Review - By Customer Backorder 00007475 0120103 ORD94156
122076	Office Meeting Sales Back Orders Review - By Customer Backorder 00012178 0120151 ORD92574
149794	Office Meeting Sales Back Orders Review - By Customer Backorder 00012178 0120151 ORD99084
128413	Office Meeting Sales Back Orders Review - By Customer Backorder 00012240 0120141 ORD94181
125485	Office Meeting Stock Processing Check Expiry Dated Stock (294)
139544	Office Meeting Stock Processing EAN code mismatch
142332	Office Meeting Any other business Envitec MySign O Oxygen Monitor
142331	Office Meeting Any other business Envitec MySign O Oxygen Monitor
142330	Office Meeting Any other business Envitec MySign O Oxygen Monitor
125550	Office Meeting Stock Processing Expired stock
150197	Office Meeting Post Market Surveillance File 15 Envitec Oxygen Sensors Medical Viamed Risk File Updated
145169	Office Meeting Post Market Surveillance File 15 Envitec Oxygen Sensors Medical Viamed Risk File Updated

Issue ID	Subject
145168	Office Meeting Post Market Surveillance File 15 Envitec Oxygen Sensors Medical Viamed Risk File Updated
136323	Office Meeting Post Market Surveillance File 15 Envitec Oxygen Sensors Medical Viamed Risk File Updated
148743	Office Meeting Non Conformance Issues Order Error : ORD98688 Goods out shipping date missed
148761	Office Meeting Non Conformance Issues Order Error : ORD98688 Goods out shipping date missed Non Conformance
147122	Office Meeting Leaflets Oxygen Monitoring Catalogue - Accessories Pack Quantities
139562	Office Meeting Price Lists UK price of 0120140
145424	Office Meeting Any other business Pricing increase 2019 - NeoPeep
135911	Office Meeting Sale or Returns Request Scanning Item to Sale or return
123647	Office Meeting Sale or Returns Request Scanning Item to Sale or return SOR861
148765	Office Meeting Any Other Business Shortages 0120151
125551	Office Meeting Stock Processing Stock items without expiry dates
112968	Office Meeting Other Technical files for Envitec branded products
128759	Office Meeting Web Site Updates Web Site Question ID 1246

Comments on Issues:

non conformances relate to order processing, not product related

Comments on Risks with Issues:

no



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Non Conformance Issues - Non Conformance Issues  
**0111211 Oxygen analyser w/o alarms - GB300.**  
Issue ID #126756  
Date Created 24/Aug/2018  
Issued To: Derek Lamb  
Completed Status: 28 Aug 2018

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Notes:

Added by Derek Lamb sent to Derek Lamb  
6 Barcode of 0120131 Connector merge Derek Lamb 22/Aug/2011

Question 6 is the incorrect part number,

should be a 0120133,

its been like this for 7 years, however the part we putting in does not fit the t-piece.

changin gthe qa records to the correct part number as of 24 08 2018

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24 Aug 2018 Derek Lamb  
As form was corr3ct we put in an extra adaptor

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28 Aug 2018 Derek Lamb  
QA form was correct we put in an extra adaptor.

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Issues:126756

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00000030 0120099 ORD94041**

Issue ID #127945

Date Created 13/Sep/2018

Issued To: General

Completed Status: 17 Sep 2018

Stock Ref: 0120099

Opera A/c: 00000030

Order Number: ORD94041

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Notes:

13 Sep 2018 02:08:23 PM Zoey Teal

See Attached Notes

Contacted the customer so they can confirm the part number is correct and also to see which delivery address to use.

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Issues:127945

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00000109 0120106 ORD94533**

Issue ID #130099

Date Created 11/Oct/2018

Issued To: General

Completed Status: 23 Oct 2018

Stock Ref: 0120106

Opera A/c: 00000109

Order Number: ORD94533

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Notes:

11 Oct 2018 05:41:14 PM Zoey Teal  
See Attached Notes

23 Oct 2018 07:51:34 AM Catherine Spence  
Shipping Tue 23 Oct 2018

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Issues:130099

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00000126 0120127 ORD96704**

Issue ID #139041

Date Created 25/Feb/2019

Issued To: General

Completed Status: 11 Mar 2019

Stock Ref: 0120127

Opera A/c: 00000126

Order Number: ORD96704

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Notes:

25 Feb 2019 07:49:11 AM Catherine Spence  
Back Order - Supplier  
requested

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Issues:139041

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00001995 0120151 ORD98688**

Issue ID #147943

Date Created 21/Jun/2019

Issued To: General

Completed Status: 04 Jul 2019

Stock Ref: 0120151

Opera A/c: 00001995

Order Number: ORD98688

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Notes:

21 Jun 2019 08:27:27 AM Catherine Spence  
Back Order - Supplier

03 Jul 2019 12:28:57 PM Sarah Walton  
We have packs of 100's in stock and some singles. Can we not use these?

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Issues:147943

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00002600 0120100 ORD94889**

Issue ID #131340

Date Created 01/Nov/2018

Issued To: General

Completed Status: 01 Nov 2018

Stock Ref: 0120100

Opera A/c: 00002600

Order Number: ORD94889

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Notes:

01 Nov 2018 08:08:32 AM Catherine Spence  
Shipping Thu 01 Nov 2018

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Issues:131340

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00004825 0120140 ORD92876**

Issue ID #123251

Date Created 02/Jul/2018

Issued To: General

Completed Status: 02 Jul 2018

Stock Ref: 0120140

Opera A/c: 00004825

Order Number: ORD92876

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Notes:

02 Jul 2018 08:51:55 AM Catherine Spence  
Shipping Mon 02 Jul 2018

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Issues:123251

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00006022 0120126 ORD98937**

Issue ID #149117

Date Created 09/Jul/2019

Issued To: General

Completed Status: 09 Jul 2019

Stock Ref: 0120126

Opera A/c: 00006022

Order Number: ORD98937

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Notes:

09 Jul 2019 07:44:59 AM Catherine Spence  
Shipping Tue 09 Jul 2019

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Issues:149117



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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00006570 0120110 ORD98253**

Issue ID #146025

Date Created 28/May/2019

Issued To: General

Completed Status: 24 Jun 2019

Stock Ref: 0120110

Opera A/c: 00006570

Order Number: ORD98253

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Notes:

28 May 2019 07:49:47 AM Catherine Spence  
Back Order - Supplier

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Issues:146025

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00006777 0120139 ORD95356**

Issue ID #133177

Date Created 29/Nov/2018

Issued To: General

Completed Status: 11 Dec 2018

Stock Ref: 0120139

Opera A/c: 00006777

Order Number: ORD95356

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Notes:

29 Nov 2018 07:49:53 AM Catherine Spence  
Back Order - Supplier

11 Dec 2018 08:12:58 AM Catherine Spence  
Shipping Tue 11 Dec 2018

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Issues:133177

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00007273 0120153 ORD93731**

Issue ID #127831

Date Created 12/Sep/2018

Issued To: General

Completed Status: 12 Sep 2018

Stock Ref: 0120153

Opera A/c: 00007273

Order Number: ORD93731

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Notes:

12 Sep 2018 07:50:55 AM Catherine Spence  
Shipping Wed 12 Sep 2018

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Issues:127831

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00007291 0120140 ORD94674**

Issue ID #130759

Date Created 23/Oct/2018

Issued To: General

Completed Status: 25 Oct 2018

Stock Ref: 0120140

Opera A/c: 00007291

Order Number: ORD94674

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Notes:

23 Oct 2018 07:59:35 AM Catherine Spence  
Back Order - Supplier

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Issues:130759

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00007475 0120103 ORD94156**

Issue ID #128318

Date Created 19/Sep/2018

Issued To: General

Completed Status: 19 Sep 2018

Stock Ref: 0120103

Opera A/c: 00007475

Order Number: ORD94156

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Notes:

19 Sep 2018 07:51:36 AM Catherine Spence  
Shipping Wed 19 Sep 2018

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Issues:128318

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00012178 0120151 ORD92574**

Issue ID #122076

Date Created 11/Jun/2018

Issued To: General

Completed Status: 20 Jun 2018

Stock Ref: 0120151

Opera A/c: 00012178

Order Number: ORD92574

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Notes:

11 Jun 2018 08:04:43 AM Catherine Spence  
Shipping Mon 11 Jun 2018

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Issues:122076

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00012178 0120151 ORD99084**

Issue ID #149794

Date Created 18/Jul/2019

Issued To: General

Completed Status: 18 Jul 2019

Stock Ref: 0120151

Opera A/c: 00012178

Order Number: ORD99084

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Notes:

18 Jul 2019 08:17:13 AM Catherine Spence  
Shipping Thu 18 Jul 2019

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Issues:149794

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VIAMED Stock Meeting - Sales Back Orders Review - By Customer

**Backorder 00012240 0120141 ORD94181**

Issue ID #128413

Date Created 20/Sep/2018

Issued To: General

Completed Status: 21 Sep 2018

Stock Ref: 0120141

Opera A/c: 00012240

Order Number: ORD94181

---

Notes:

20 Sep 2018 09:57:14 AM Zoey Teal  
Part numbers confirmed. OK to ship the order.

---

Issues:128413



---

VIAMED Stock Meeting - Stock Processing

**Check Expiry Dated Stock (294)**

Issue ID #125485

Date Created 06/Aug/2018

Issued To: Robert Connor

Completed Status: 09 Aug 2018

---

Notes:

System Generated

Stock Book -> Expiry Dates

check for out of date stock

---

06 Aug 2018 Robert Connor

Created Related Issue #125550

Added by Robert Connor sent to Derek Lamb

Expired stock located and removed from sellable shelf;

0120103 15mm T piece barcode IDs 892029, 891994, 892028, 892019, 891996, 892026, 892017

1969 box of connectors, IDs 609708, 609707

---

06 Aug 2018 Robert Connor

Done.

---

Issues:125485

---

VIAMED Stock Meeting - Stock Processing

**EAN code mismatch**

Issue ID #139544

Date Created 04/Mar/2019

Issued To: Derek Lamb

Completed Status: 04 Mar 2019

---

Notes:

Added by Robert Connor sent to Derek Lamb

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

p/n 1974 Connector 22M/15F box of 45 has own EAN code 05030267005925

single p/n 0120127 has EAN code 05030267057658

p/n 1802 T-piece 15m - 15F - 15F box of 40 has own EAN code 05030267002863

single p/n 0120103 has EAN code 05030267055104

---

Issues:139544

---

VIAMED Sales And Marketing - Any other business

**Envitec MySign O Oxygen Monitor**

Issue ID #142332

Date Created 10/Apr/2019

Issued To: Steve Hardaker

Completed Status: Still Outstanding

---

**Notes:**

Copy Issue Main Issue #142330

Added by Steve Nixon sent to Catrin Hird

As discussed please prepare technical and marketing files for the MySign O.

Catrin, please generate a leaflet and section on the web site.

I'll confirm the pricing soon. I have provisionally added a Euro distributor price (for Medivent via Ryan).

Opera Envitec

0111276 1001825 MySign O

0120100 T-Adapter

0120399 46-006005 T-Adapter. Pack of 5

0120092 Flow diverter (single unit)

0120093 01-002173 Flow diverter. Pack of 10

0121350 Oxygen sensor cable

0121351 1001801 Clamp

0121352 1001829 Power supply

0121354 1001830 Operating manual CD

0121353 1001815 Data cable

0110560 01-00-0114 Oxygen sensor

0131900 1001764 Integrated stand (replacement part)

0191207 Leaflet

Envitec leaflet on their web site.

Look at Pro-Act web site.

---

15 Apr 2019 Steve Hardaker

Have started a project in the project manager and a technical file, which I will add to as information is located or generated.

---

15 Apr 2019 Steve Nixon

Additional parts

0131901 1001734 Rechargeable battery

0121355 1002080 Software

---

15 Apr 2019 Steve Nixon

Provisional price list calculations attached.

---

Issues:142332

---

VIAMED Sales And Marketing - Any other business

**Envitec MySign O Oxygen Monitor**

Issue ID #142331

Date Created 10/Apr/2019

Issued To: Derek Lamb

Completed Status: 24 Apr 2019

---

**Notes:**

Copy Issue Main Issue #142330

Added by Steve Nixon sent to Catrin Hird

As discussed please prepare technical and marketing files for the MySign O.

Catrin, please generate a leaflet and section on the web site.

I'll confirm the pricing soon. I have provisionally added a Euro distributor price (for Medivent via Ryan).

Opera Envitec

0111276 1001825 MySign O

0120100 T-Adapter

0120399 46-006005 T-Adapter. Pack of 5

0120092 Flow diverter (single unit)

0120093 01-002173 Flow diverter. Pack of 10

0121350 Oxygen sensor cable

0121351 1001801 Clamp

0121352 1001829 Power supply

0121354 1001830 Operating manual CD

0121353 1001815 Data cable

0110560 01-00-0114 Oxygen sensor

0131900 1001764 Integrated stand (replacement part)

0191207 Leaflet

Envitec leaflet on their web site.

Look at Pro-Act web site.

---

12 Apr 2019 Derek Lamb

Pro-act have very little information on the website regarding envitec o2 monitors.

Sat with SH yesterday and created the project file for the mysign,

---

Issues:142331

---

VIAMED Sales And Marketing - Any other business

**Envitec MySign O Oxygen Monitor**

Issue ID #142330

Date Created 10/Apr/2019

Issued To: Catrin Hird

Completed Status: 24 Apr 2019

Linked Files

12 Apr 2019 Proact webpage

15 Apr 2019 MySign O price list calculations 2019-04-15

16 Apr 2019 Envitec MySign O Leaflet

16 Apr 2019 Envitec MySign O Regulatory Standards Letter

16 Apr 2019 Envitec MySign O DofC

16 Apr 2019 MySign O Operator Manual

---

Notes:

Added by Steve Nixon sent to Catrin Hird

As discussed please prepare technical and marketing files for the MySign O.

Catrin, please generate a leaflet and section on the web site.

I'll confirm the pricing soon. I have provisionally added a Euro distributor price (for Medivent via Ryan).

Opera Envitec

0111276 1001825 MySign O

0120100 T-Adapter

0120399 46-006005 T-Adapter. Pack of 5

0120092 Flow diverter (single unit)

0120093 01-002173 Flow diverter. Pack of 10

0121350 Oxygen sensor cable

0121351 1001801 Clamp

0121352 1001829 Power supply

0121354 1001830 Operating manual CD

0121353 1001815 Data cable

0110560 01-00-0114 Oxygen sensor

0131900 1001764 Integrated stand (replacement part)

0191207 Leaflet

Envitec leaflet on their web site.

Look at Pro-Act web site.

---

16 Apr 2019 Catrin Hird

Documents from email linked to issue.

Awaiting reply to SJH email to SN regarding use of device when connected to power supply. - 12/04/19 09:44

If I'm reading the other email from Jessica correctly, the unit can be charged via USB or mains power supply when connected to the patient but can not be charged via USB when connected to the patient??

There is a charge time stated on the leaflet as 4 hours, is this applicable to the mains and USB or do they charge at different rates?

What is the warranty of the device, the sensor is 15 months as per existing literature?

If you would like me to ask Jessica directly these questions please let me know.

Also price missing for 0131900 USD end user. Are the rest of the prices now correct?

---

16 Apr 2019 Catrin Hird  
Linked to marketing job for leaflet.

---

16 Apr 2019 Steve Nixon  
Awaiting PSU statement from Envitec.

Added 0131900, also added missing 0131901.

---

16 Apr 2019 Catrin Hird  
0131901 Rechargeable spelt incorrectly, should be rechargeable.

---

Issues:142330

---

VIAMED Stock Meeting - Stock Processing

**Expired stock**

Issue ID #125550

Date Created 06/Aug/2018

Issued To: Derek Lamb

Completed Status: 06 Aug 2018

---

Notes:

Added by Robert Connor sent to Derek Lamb

Expired stock located and removed from sellable shelf;

0120103 15mm T piece barcode IDs 892029, 891994, 892028, 892019, 891996, 892026, 892017

1969 box of connectors, IDs 609708, 609707

---

06 Aug 2018 Derek Lamb

blocked them removed from intrastats,

guess they need to be adjusted out of opera too

---

06 Aug 2018 Robert Connor

Ok, adjusted opera too, thank you.

---

Issues:125550

---

VIAMED Sales And Marketing - Post Market Surveillance

**File 15 Envitec Oxygen Sensors Medical Viamed Risk File Updated**

Issue ID #150197

Date Created 24/Jul/2019

Issued To: Derek Lamb

Completed Status: Still Outstanding

Stock Ref: 0120100

---

**Notes:**

Risk file has changed, VM3COP27.12 Needs reviewing for 15 Envitec Oxygen Sensors Medical Viamed as the Risk assesment has changed

---

Issues:150197



---

VIAMED Sales And Marketing - Post Market Surveillance

**File 15 Envitec Oxygen Sensors Medical Viamed Risk File Updated**

Issue ID #145169

Date Created 16/May/2019

Issued To: Derek Lamb

Completed Status: 17 May 2019

Stock Ref: 0120100

---

**Notes:**

Risk file has changed, VM3COP27.12 Needs reviewing for 15 Envitec Oxygen Sensors Medical Viamed as the Risk assesment has changed

---

16 May 2019 Derek Lamb  
reviewed

---

Issues:145169

---

VIAMED Sales And Marketing - Post Market Surveillance

**File 15 Envitec Oxygen Sensors Medical Viamed Risk File Updated**

Issue ID #145168

Date Created 16/May/2019

Issued To: Derek Lamb

Completed Status: 17 May 2019

Stock Ref: 0120100

---

**Notes:**

Risk file has changed, VM3COP27.12 Needs reviewing for 15 Envitec Oxygen Sensors Medical Viamed as the Risk assesment has changed

---

16 May 2019 Derek Lamb  
reviewed

---

Issues:145168

---

VIAMED Sales And Marketing - Post Market Surveillance

**File 15 Envitec Oxygen Sensors Medical Viamed Risk File Updated**

Issue ID #136323

Date Created 16/Jan/2019

Issued To: Derek Lamb

Completed Status: 17 Jan 2019

Stock Ref: 0120100

---

**Notes:**

Risk file has changed, VM3COP27.12 Needs reviewing for 15 Envitec Oxygen Sensors Medical Viamed as the Risk assesment has changed

---

Issues:136323

---

Non Conformance Issues - Non Conformance Issues

**Order Error : ORD98688 Goods out shipping date missed**

Issue ID #148743

Date Created 03/Jul/2019

Issued To: Helen Lamb

Completed Status: 03 Jul 2019

---

**Notes:**

Auto Issue from Error Log ORD98688

Order Entered by Zoey Teal

Order Checked by Sarah Walton

Goods Out

Error was Goods out shipping date missed

Fault:

Order is for part number 0120121 (pks of 20) none of these in stock, however we have plenty of the pks of 100 and some singles

Possible Fix

Goods out team could do with a rolling issue to check the back order lists so that these would get picked up and not be missed.

---

03 Jul 2019 Helen Lamb

Created Related Issue #148761

Added by Helen Lamb sent to Derek Lamb

Suggestion for rolling issue. Thoughts. send issue back to me when you had a look please

#148743

Order Error : ORD98688 Goods Out Shipping Date Missed :Issue Visable to: Auto\_Issue AND Helen Lamb

Viamed Non Conformance Issues Non Conformance Issues

# 148743 Adhoc Meeting - Created: 03 Jul 2019 12:39:35 PM By Auto\_Issue

Set to User: Helen Lamb

.Auto Issue from Error Log ORD98688

Order Entered by Zoey Teal

Order Checked by Sarah Walton

Goods Out

Error was Goods out shipping date missed

Fault:

Order is for part number 0120121 (pks of 20) none of these in stock, however we have plenty of the pks of 100 and some singles

Possible Fix

Goods out team could do with a rolling issue to check the back order lists so that these would get picked up and not be missed.

---

Issues:148743

---

Non Conformance Issues - Non Conformance Issues

**Order Error : ORD98688 Goods out shipping date missed Non Conformance**

Issue ID #148761

Date Created 03/Jul/2019

Issued To: Derek Lamb

Completed Status: 09 Jul 2019

---

Notes:

Added by Helen Lamb sent to Derek Lamb

Suggestion for rolling issue. Thoughts. send issue back to me when you had a look please

#148743

Order Error : ORD98688 Goods Out Shipping Date Missed :Issue Visable to: Auto\_Issue AND Helen Lamb  
Viamed Non Conformance Issues Non Conformance Issues

# 148743 Adhoc Meeting - Created: 03 Jul 2019 12:39:35 PM By Auto\_Issue

Set to User: Helen Lamb

.Auto Issue from Error Log ORD98688

Order Entered by Zoey Teal

Order Checked by Sarah Walton

Goods Out

Error was Goods out shipping date missed

Fault:

Order is for part number 0120121 (pks of 20) none of these in stock, however we have plenty of the pks of 100 and some singles

Possible Fix

Goods out team could do with a rolling issue to check the back order lists so that these would get picked up and not be missed.

---

03 Jul 2019 Derek Lamb

Created Related Issue #148763

Added by Derek Lamb sent to Derek Lamb

See Main issue suggestion

---

03 Jul 2019 Derek Lamb

created myself an Issue to follow up,

---

05 Jul 2019 Derek Lamb

---

Issues:148761

---

VIAMED Sales And Marketing - Leaflets

**Oxygen Monitoring Catalogue - Accessories Pack Quantities**

Issue ID #147122

Date Created 12/Jun/2019

Issued To: Steve Nixon

Completed Status: Still Outstanding

Linked Files

12 Jun 2019 Oxygen Monitoring Catalogue 2019-06 WIP

---

**Notes:**

Added by Catrin Hird sent to Steve Nixon

Please can you clarify which of the following part numbers we will be able to sell as singles and which will have to be box quantities:

0120100

0120106

0120107

0120104

0120108

0120109

0120105 - discontinued?

0120103

0120110 - only sold as separate parts? Presume will have to be the box quantity though.

0120165

0120166

0120101

0120102

0120120

PP1968

0120125

0120126

0120127

0120128

0120129

0120130

0120131

0120133

0120139

0120140

0120141

0120142

If the supplier is able to produce the part number for a single and we order 50 x said part number could we then sell as singles?

Leaflet attached for reference.

---

Issues:147122

---

VIAMED Sales And Marketing - Price Lists UK

**price of 0120140**

Issue ID #139562

Date Created 04/Mar/2019

Issued To: Catrin Hird

Completed Status: 07 Mar 2019

---

Notes:

Added by Kate Griffiths sent to Catrin Hird

Hi Catrin. I believe the price of the 0120140 has increased. The price list (in infant resus catalogue) shows £2.35. Intrastats says £3

---

04 Mar 2019 Kate Griffiths

Price lists is NeoPEEP GBP price list 2018-03-26. under NeoPEEP & Marshall.

---

05 Mar 2019 Catrin Hird

Thank you, I have updated the price list and put in Z for L. Will ask SN to update L today.

---

07 Mar 2019 Kate Griffiths

done

---

Issues:139562

---

VIAMED Sales And Marketing - Any other business

**Pricing increase 2019 - NeoPeep**

Issue ID #145424

Date Created 20/May/2019

Issued To: Catrin Hird

Completed Status: 31 May 2019

Linked Files

21 May 2019 5% Increase Calculations 2019-05-21

22 May 2019 5% Increase Calculations 2019-05-22

---

**Notes:**

Added by Steve Nixon sent to Catrin Hird

Add 5% to GBP list prices for:

product, accessories and parts

---

21 May 2019 Catrin Hird

Increased by 5%, see attached spreadsheet (this covers all prices which were to be increased by 55)

---

22 May 2019 Catrin Hird

Also added 0120142, amended spreadsheet attached.

---

Issues:145424



---

VIAMED Stock Meeting - Sale or Returns

**Request Scanning Item to Sale or return**

Issue ID #135911

Date Created 10/Jan/2019

Issued To: Steve Hardaker

Completed Status: 14 Jan 2019

---

**Notes:**

Added by Kate Griffiths sent to Catherine Spence

Please scan to Sale or Returns Location ID34132 Stock Reference: 0120140 x1 and 0120141 x1.  
SOR893. A/c 00001310

---

11 Jan 2019 Catherine Spence

Next Action Changed From Catherine Spence To Steve Hardaker 1317314  
1314041

---

11 Jan 2019 Steve Hardaker  
Done, thanks. Sent on SOR893.

---

14 Jan 2019 Kate Griffiths  
done . finished by SH.

---

Issues:135911

---

VIAMED Stock Meeting - Sale or Returns

**Request Scanning Item to Sale or return SOR861**

Issue ID #123647

Date Created 09/Jul/2018

Issued To: Catherine Spence

Completed Status: 11 Jul 2018

---

Notes:

Added by Zoey Teal sent to Catherine Spence

Please scan to Sale or Returns Location ID34132 Stock Reference: SOR861

1 X 120139

1 X 0120140

1 X 0120141

---

10 Jul 2018 Catherine Spence

200436

1242467

950016

---

11 Jul 2018 Zoey Teal

COMPLETED

---

Issues:123647

---

VIAMED Stock Meeting - Any Other Business

**Shortages 0120151**

Issue ID #148765

Date Created 03/Jul/2019

Issued To: Catherine Spence

Completed Status: 04 Jul 2019

---

Notes:

Added by Steve Nixon sent to Catherine Spence  
Looks like we are short of 2 x 0120151 (pack of 20)

Suggest to break down a pack of 100 (0120153) into 20s.

---

04 Jul 2019 Catherine Spence  
already done, and order has been dispatched

---

04 Jul 2019 Steve Nixon  
Thanks

---

Issues:148765

---

VIAMED Stock Meeting - Stock Processing

**Stock items without expiry dates**

Issue ID #125551

Date Created 06/Aug/2018

Issued To: Derek Lamb

Completed Status: 26 Nov 2018

---

**Notes:**

Added by Robert Connor sent to Derek Lamb

I have been examining the T pieces in stock for expiry dates and it looks like everything from Intersurgical comes with manufacture and expiry date printed on the individual packets, but anything from instrumentation industries only has a batch number.

Part numbers with no expiry dates:

1993

A-11088

3210015

0120125, 128, 129, 130, 131, 140, 151, 152

0120200, 201, 202, 203, 205, 208

0120164

---

26 Nov 2018 Robert Connor

---

Issues:125551

---

VIAMED Management Meeting - Other  
**Technical files for Envitec branded products**

Issue ID #112968

Date Created 23/Jan/2018

Issued To: Derek Lamb

Completed Status: 24 Aug 2018

---

**Notes:**

Added by Steve Nixon sent to Derek Lamb

Envitec branded Medical sensors and products. At the moment it only covers:

0110560 01-00-0114 OOM111

0120091 01-002173 Flow diverter

0120100 46-006005 T adapter

Envitec branded Automotive/Industrial sensors. At the moment it only covers:

0110660 46-00-0021 OI103

0111275 46-00-0021 OxiQuant S

0120091 01-002173 Flow diverter

0120100 46-006005 T adapter

---

16 Aug 2018 Derek Lamb

sorry steve I left this issue too long, not sure what I'm doing with the information

---

16 Aug 2018 Steve Nixon

We should have a tech file for Envitec branded products, we are just selling the ones above at the moment. Remember we have a separate contract agreement to cover all Envitec branded products.

---

Issues:112968

---

Non Conforming Stock Transfers. (QC19) - Web Site Updates

**Web Site Question ID 1246**

Issue ID #128759

Date Created 24/Sep/2018

Issued To: Kate Griffiths

Completed Status: 24 Sep 2018

---

**Notes:**

Web Site Question ID 1246

24/09/18

Saleh.Algarni@nottingham.ac.uk

Information Request to Viamed Limited at the <https://www.viamed.co.uk/uk/> WebSite

0120106 `T` Adapter for use with 15mm O.D. flow diverters

Saleh

Nottingham University Hospital

Saleh.Algarni@nottingham.ac.uk

United Kingdom EU

Type: Pricing

Hi

I would like to get quote for ordering quantity of 100 items for this part.

Best Regards

Sal

Request further Information on

---

24 Sep 2018 Kate Griffiths

done. Asked for further information as Notts Uni Hosp. KG 24.9.18

---

24 Sep 2018 Kate Griffiths

done. Asked for further information as Notts Uni Hosp. KG 24.9.18

---

Issues:128759

# 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 Plastic T Piece.  
no reports no studys found

## 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 simple Plastic T Piece.  
no reports no studys found