



VIA MED

Oxygen Tents/Hoods Tanda

Enclosures to enable oxygen enriched air and humidity
to be supplied to the patients head only

Class IIa
Via Rule Rule 2
Assesment Route Annex II
NBOG MD 0100

Carried out by Derek Lamb
25 / 10 / 18



VIA MED

-  Stock References Review
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Stock References Review

Stock Reference	Description
PP1968	Connector - 22mm Oxygen Stem.
PP8000	Oxygen Hood - Size 1 with sliding front
PP8000/SF	Sliding Front for use with PP8000/PP8020
PP8020	Oxygen Hood - Size 1 with sliding front
PP8050	Oxygen Hood - Size 2 with sliding front
PP8050/SF	Sliding Front for use with PP8050/PP8055
PP8055	Oxygen Hood - Size 2 with sliding front
PP8060	Oxygen Hood - Size 3 with sliding front
PP8060/SF	Sliding Front for use with PP8060/PP8065
PP8065	Oxygen Hood - Size 3 with sliding front
PP8066	Sliding Front Retaining Knob
PP8509	Phototherapy Light Shield/Oxygen Hood.
PP8533	Phototherapy Light Shield/Oxygen Hood.
PP8540	Phototherapy Light Shield/Oxygen Hood.
PP8562	Phototherapy Light Shield/Oxygen Hood.
PP8565	Phototherapy Light Shield/Oxygen Hood.
PP8589	Oxygen Hood - Size 4 with sliding front
PP8589/SF	Sliding Front for use with PP8589/PP8715
PP8591	Special Made To Customer Spec
PP8593	Oxygen headbox made to customer`s
PP85XX	Special Made to Customer Spec
PP8687	Oxygen hood - special. With side doors.
PP8715	Oxygen Hood - Size 4 with sliding front
PP8729	Oxygen hood - special.
PP8730	Oxygen hood - special.
PP8744	Oxygen hood - special.
PP8746	Oxygen hood - special.
PP8747	Oxygen hood - special.
PP8748	Oxygen hood - special.
PP8752	Oxygen hood - special.
PP8753	Oxygen hood - special.
PP8754	Oxygen hood - special.
PP8755	Oxygen hood - special.
PP8756	Oxygen hood - special.
PP8757	Oxygen hood - special.
PP8758	Oxygen hood - special.
PP8759	Oxygen hood - special.
PP8760	Oxygen hood - special.
PP8771	Oxygen Hood - Special
PP8772	Oxygen hood - special.
PP8773	Oxygen hood - special.
PP8774	Oxygen Hood - special.

Stock Reference	Description
PP8775	Oxygen Hood - special.
PP8780	Oxygen Hood - Size 1 without sliding
PP8781	Oxygen Hood - Size 2 without sliding
PP8782	Oxygen Hood - Size 3 without sliding
PP8783	Oxygen Hood - Size 1 without sliding
PP8784	Oxygen Hood - Size 2 without sliding
PP8785	Oxygen Hood - Size 3 without sliding
PP8791	Oxygen Hood - Special

Comments on Stock references review:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
PP8000	Oxygen Hood - Size 1 wi	00009022	PP8000	Tanda Engineering Ltd	B
PP8020	Oxygen Hood - Size 1 wi	00009022	PP8020	Tanda Engineering Ltd	B
PP8050	Oxygen Hood - Size 2 wi	00009022	PP8050	Tanda Engineering Ltd	B
PP8050/SF	Sliding Front for use wi	00009022	PP8050/SF	Tanda Engineering Ltd	B
PP8055	Oxygen Hood - Size 2 wi	00009022	PP8055	Tanda Engineering Ltd	B
PP8060	Oxygen Hood - Size 3 wi	00009022	PP8060	Tanda Engineering Ltd	B
PP8065	Oxygen Hood - Size 3 wi	00009022	PP8065	Tanda Engineering Ltd	B
PP8066	Sliding Front Retaining	00009022		Tanda Engineering Ltd	B
PP8509	Phototherapy Light Shiel	00009022	PP8509	Tanda Engineering Ltd	B
PP8533	Phototherapy Light Shiel	00009022	PP8533	Tanda Engineering Ltd	B
PP8562	Phototherapy Light Shiel	00009022	PP8060/A	Tanda Engineering Ltd	B
PP8589	Oxygen Hood - Size 4 wi	00009022	PP8589	Tanda Engineering Ltd	B
PP8593	Oxygen headbox made to c	00009022	PP8593	Tanda Engineering Ltd	B
PP8687	Oxygen hood - special.	00009022	PP8687	Tanda Engineering Ltd	B
PP8715	Oxygen Hood - Size 4 wi	00009022	PP8715	Tanda Engineering Ltd	B
PP8729	Oxygen hood - special.	00009022	PP8729	Tanda Engineering Ltd	B
PP8730	Oxygen hood - special.	00009022	PP8730	Tanda Engineering Ltd	B
PP8744	Oxygen hood - special.	00009022	PP8744	Tanda Engineering Ltd	B
PP8746	Oxygen hood - special.	00009022	PP8746	Tanda Engineering Ltd	B
PP8747	Oxygen hood - special.	00009022	PP8747	Tanda Engineering Ltd	B
PP8748	Oxygen hood - special.	00009022	PP8748	Tanda Engineering Ltd	B
PP8754	Oxygen hood - special.	00009022	PP8754	Tanda Engineering Ltd	B
PP8755	Oxygen hood - special.	00009022	PP8755	Tanda Engineering Ltd	B
PP8756	Oxygen hood - special.	00009022	PP8756	Tanda Engineering Ltd	B
PP8757	Oxygen hood - special.	00009022	PP8757	Tanda Engineering Ltd	B
PP8758	Oxygen hood - special.	00009022	PP8758	Tanda Engineering Ltd	B
PP8759	Oxygen hood - special.	00009022	PP8759	Tanda Engineering Ltd	B
PP8760	Oxygen hood - special.	00009022	PP8760	Tanda Engineering Ltd	B
PP8771	Oxygen Hood - Special	00009022	PP8771	Tanda Engineering Ltd	B
PP8774	Oxygen Hood - special.	00009022	PP8774	Tanda Engineering Ltd	B
PP8775	Oxygen Hood - special.	00009022	PP8775	Tanda Engineering Ltd	B
PP8781	Oxygen Hood - Size 2 wi	00009022		Tanda Engineering Ltd	B
PP8782	Oxygen Hood - Size 3 wi	00009022		Tanda Engineering Ltd	B
PP8791	Oxygen Hood - Special	00009022	PP8791	Tanda Engineering Ltd	B
PP1968	Connector - 22mm Oxygen	00009082	1968000	Intersurgical Ltd	B

Comments on Suppliers:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Sales Information

Stock Reference	Description	2012	2013	2014	2015	2016	2017	2018
PP1968	Connector - 22mm Oxygen	48	172	35	151	16	30	
PP8000	Oxygen Hood - Size 1 wi	14	9	38	13	10	9	
PP8000/SF	Sliding Front for use with PP8000/PP8020							
PP8020	Oxygen Hood - Size 1 wi		1	13	18	5	2	
PP8050	Oxygen Hood - Size 2 wi	98	8	39	16	15	4	
PP8050/SF	Sliding Front for use wi		1					
PP8055	Oxygen Hood - Size 2 wi	1	12	7	4	10		
PP8060	Oxygen Hood - Size 3 wi	27	21	22	28	25	5	11
PP8060/SF	Sliding Front for use with PP8060/PP8065							
PP8065	Oxygen Hood - Size 3 wi	14	9	8	7	9	3	
PP8066	Sliding Front Retaining		2	2				
PP8509	Phototherapy Light Shiel		1					
PP8533	Phototherapy Light Shiel		20	81	22	30	70	
PP8540	Phototherapy Light Shield/Oxygen Hood.							
PP8562	Phototherapy Light Shiel	1			4			
PP8565	Phototherapy Light Shield/Oxygen Hood.							
PP8589	Oxygen Hood - Size 4 wi	24	33	30	25	15	3	13
PP8589/SF	Sliding Front for use with PP8589/PP8715							
PP8591	Special Made To Customer Spec							
PP8593	Oxygen headbox made to c							
PP85XX	Special Made to Cusomer Spec							
PP8687	Oxygen hood - special.	2						
PP8715	Oxygen Hood - Size 4 wi	2	12	7	4	1	2	
PP8729	Oxygen hood - special.							
PP8730	Oxygen hood - special.							
PP8744	Oxygen hood - special.							
PP8746	Oxygen hood - special.							
PP8747	Oxygen hood - special.							
PP8748	Oxygen hood - special.							
PP8752	Oxygen hood - special.							
PP8753	Oxygen hood - special.							
PP8754	Oxygen hood - special.							
PP8755	Oxygen hood - special.							
PP8756	Oxygen hood - special.							
PP8757	Oxygen hood - special.							
PP8758	Oxygen hood - special.							
PP8759	Oxygen hood - special.							
PP8760	Oxygen hood - special.							
PP8771	Oxygen Hood - Special		3	3				
PP8772	Oxygen hood - special.							
PP8773	Oxygen hood - special.							
PP8774	Oxygen Hood - special.	2						

Stock Reference	Description	2012	2013	2014	2015	2016	2017	2018
PP8775	Oxygen Hood - special.							
PP8780	Oxygen Hood - Size 1 without sliding							
PP8781	Oxygen Hood - Size 2 wi		5					
PP8782	Oxygen Hood - Size 3 wi		5					
PP8783	Oxygen Hood - Size 1 without sliding							
PP8784	Oxygen Hood - Size 2 without sliding							
PP8785	Oxygen Hood - Size 3 without sliding							
PP8791	Oxygen Hood - Special				2			

Comments on Sales Information:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Countries Review

Country	2012	2013	2014	2015	2016	2017	2018
AU Austria			[X]				
B Belgium	[X]	[X]	[X]	[X]	[X]	[X]	
BA Kingdom of Bahrain	[X]			[X]			
BO Bosnia				[X]			
CHA Channel Islands							
CY Cyprus				[X]	[X]		
EC Ecuador			[X]				
F France	[X]			[X]	[X]		
GI Gibraltar		[X]					
GR Greece			[X]				
IN India		[X]					
IRE Ireland	[X]	[X]	[X]	[X]	[X]		
IT Italy							
JO Jordan							
KU Kuwait				[X]			
MA Malaysia							
MAC Macedonia		[X]		[X]			
MAU Mauritius					[X]	[X]	
MO Morocco							
MOL MOLDOVA		[X]	[X]				
NE Netherlands							
NI Northern Ireland	[X]	[X]					
OM Oman	[X]	[X]	[X]	[X]	[X]	[X]	
P Poland		[X]					
PO Portugal				[X]			
Q Qatar	[X]						
RO Romania				[X]	[X]		[X]
RU Russia		[X]	[X]	[X]	[X]	[X]	
SC Scotland	[X]		[X]				
SP Spain	[X]	[X]			[X]	[X]	[X]
SW Sweden							
T Turkey							
TT Trinidad and Tobago		[X]					
UAE U A E		[X]					
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	
YE Yemen			[X]				

Comments on Sales to Countries:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2012	2013	2014	2015	2016	2017	2018
PP8050	Unchecked - Returned To Stock			1				
PP8055	New							
PP8060	Unchecked - Returned To Stock							
PP8533	No Fault Found			1				
PP8533	Unchecked - Returned To Stock						1	
PP8589	Hair Line Crack						2	
PP8715	New							
PP8715	Unchecked - Returned To Stock							
PP8757	No Fault Return To Stock							
PP8758	No Fault Return To Stock							

Comments on Returns:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Comments on Risks with Returns and Potential Re-work:

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Comments on Risks with Design Changes:

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
14778	Oxygen Hoods Instructions for Use User Manual	19/02/15

Comments on User Instructions:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Comments on Risks User Instructions:

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
16792	Head Box Oxygen Hoods Labels	20/04/16
9526	Oxygen Hoods Labels 0430011	18/10/11
9169	No accessory labels	18/10/11
8523	Oxygen Hoods Labels	13/07/11
8521	Oxygen Hoods Labels 0430010	13/07/11

Comments on Labels:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Comments on Risks Labels:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
24894	Oxygen Tents/Hoods Tanda Clinical Trials Reports papers	17/01/18
24639	Oxygen Tents/Hoods Tanda Clinical evaluation	12/12/17
23878	Oxygen Tents/Hoods Tanda Design Input Device Design Theory Oxy...	13/11/17
22393	Oxygen Hoods Clinical Trials Reports Reviews and Post Market Sur...	02/10/17

Comments on Document Changes:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Comments on Risks with Document Changes:

Internal Issues Review

Number of Issues reviewed: 19

Issue ID	Subject
107589	Office Meeting Sales Back Orders Review - By Customer Backorder 00000450 PP8050 ORD89232
107590	Office Meeting Sales Back Orders Review - By Customer Backorder 00000450 PP8060 ORD89233
108440	Office Meeting Sales Back Orders Review - By Customer Backorder 00000620 PP8065 ORD89413
104555	Office Meeting Sales Back Orders Review - By Customer Backorder 00001310 PP8000 ORD88632
108233	Office Meeting Sales Back Orders Review - By Customer Backorder 00005117 PP8589 ORD89377
108511	Office Meeting Sales Back Orders Review - By Customer Backorder 00006304 PP8060 ORD89378
105321	Office Meeting Sales Back Orders Review - By Customer Backorder 00007029 PP8000 ORD88793
109343	Office Meeting Sales Back Orders Review - By Customer Backorder 00007273 PP8533 ORD89109
106398	Office Meeting Stock Processing EAN code mismatch
107518	Office Meeting Stock Processing Pallet dims
105619	Office Meeting Back Order Report POR11477 PP8000 //
105623	Office Meeting Back Order Report POR11478 PP1968 //
107344	Office Meeting Back Order Report POR11500 PP8533 //
107690	Office Meeting Back Order Report POR11515 PP1968 //
110475	Office Meeting Back Order Report POR11518 PP8050 //
110468	Office Meeting Back Order Report POR11518 PP8050 //
108706	Office Meeting Back Order Report POR11529 PP8060 //
108707	Office Meeting Back Order Report POR11529 PP8065 //
105107	Office Meeting Stock Processing Warehouse Request

Comments on Issues:

we have ceased selling these devices due to MHRA / BSI regulations and costs

Comments on Risks with Issues:

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00000450 PP8050 ORD89232

Issue ID #107589

Date Created 08/Nov/2017

Issued To: General

Completed Status: 28 Dec 2017

Stock Ref: PP8050

Opera A/c: 00000450

Order Number: ORD89232

Notes:

08 Nov 2017 09:07:41 AM Zoey Teal
Advised £20 carriage charge

21 Nov 2017 07:54:17 AM Catherine Spence
Back Order - Supplier

30 Nov 2017 09:17:50 AM Zoey Teal
Advised lead time

28 Dec 2017 08:19:01 AM Catherine Spence
Shipping Thu 28 Dec 2017

Issues:107589

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00000450 PP8060 ORD89233

Issue ID #107590

Date Created 08/Nov/2017

Issued To: General

Completed Status: 09 Nov 2017

Stock Ref: PP8060

Opera A/c: 00000450

Order Number: ORD89233

Notes:

08 Nov 2017 09:07:49 AM Zoey Teal
Advised £20 carriage charge

Issues:107590

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00000620 PP8065 ORD89413

Issue ID #108440

Date Created 17/Nov/2017

Issued To: General

Completed Status: 28 Dec 2017

Stock Ref: PP8065

Opera A/c: 00000620

Order Number: ORD89413

Notes:

17 Nov 2017 04:50:09 PM Sophie Lines

Incorrect price. Awaiting response from Ali Hasan - he has emailed end user but hasn't come back yet

Issues:108440

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00001310 PP8000 ORD88632

Issue ID #104555

Date Created 04/Oct/2017

Issued To: General

Completed Status: 06 Oct 2017

Stock Ref: PP8000

Opera A/c: 00001310

Order Number: ORD88632

Notes:

04 Oct 2017 11:50:34 AM Emily Hanson
emailed about wrong price/carriage

05 Oct 2017 09:15:12 AM Emily Hanson
okay to fo

Issues:104555

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00005117 PP8589 ORD89377

Issue ID #108233

Date Created 15/Nov/2017

Issued To: General

Completed Status: 16 Nov 2017

Stock Ref: PP8589

Opera A/c: 00005117

Order Number: ORD89377

Notes:

15 Nov 2017 03:06:54 PM Emily Hanson
okay to gogog

Issues:108233

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00006304 PP8060 ORD89378

Issue ID #108511

Date Created 20/Nov/2017

Issued To: General

Completed Status: 03 Jan 2018

Stock Ref: PP8060

Opera A/c: 00006304

Order Number: ORD89378

Notes:

20 Nov 2017 08:16:52 AM Catherine Spence
Back Order - Supplier

30 Nov 2017 08:41:44 AM Zoey Teal
Aware of lead time.

Issues:108511

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007029 PP8000 ORD88793

Issue ID #105321

Date Created 13/Oct/2017

Issued To: General

Completed Status: 23 Nov 2017

Stock Ref: PP8000

Opera A/c: 00007029

Order Number: ORD88793

Notes:

13 Oct 2017 08:28:39 AM Catherine Spence
Back Order - Supplier

02 Nov 2017 02:03:54 PM Sarah Walton
See Attached Notes
Customer aware of the lead time.

06 Nov 2017 07:58:42 AM Catherine Spence
Back Order - Supplier

Issues:105321

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00007273 PP8533 ORD89109

Issue ID #109343

Date Created 29/Nov/2017

Issued To: General

Completed Status: 05 Dec 2017

Stock Ref: PP8533

Opera A/c: 00007273

Order Number: ORD89109

Notes:

29 Nov 2017 03:19:55 PM Katie Evans

See Attached Notes

Aware of lead time

29 Nov 2017 03:20:06 PM Katie Evans

Part shipped 28/11/2017

05 Dec 2017 10:31:07 AM Katie Evans

Moved to PRO04751 as per customer request

Issues:109343

VIAMED Stock Meeting - Stock Processing

EAN code mismatch

Issue ID #106398

Date Created 24/Oct/2017

Issued To: Derek Lamb

Completed Status: 24 Oct 2017

Notes:

Added by Robert Connor sent to Derek Lamb

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

PP1968 - oxygen stem. EAN code does not match that from supplier, should be 5030267057511

Issues:106398

VIAMED Stock Meeting - Stock Processing

Pallet dims

Issue ID #107518

Date Created 07/Nov/2017

Issued To: Sarah Walton

Completed Status: 09 Nov 2017

Notes:

Added by Jonathan Connor sent to Sarah Walton
Artisans. 10 * PP8060 and 13*PP8589

2 pallets. Each would be 1.2*1*1.6(height) m

09 Nov 2017 Sarah Walton
Done, thanks

09 Nov 2017 Jonathan Connor
thanks

Issues:107518

- Back Order Report

POR11477 PP8000 //

Issue ID #105619

Date Created 17/Oct/2017

Issued To: Jonathan Connor

Completed Status: 17 Oct 2017

Notes:

POR11477 PP8000 Estimated ship to us date changed to / /

Issues:105619

- Back Order Report

POR11478 PP1968 //

Issue ID #105623

Date Created 17/Oct/2017

Issued To: Jonathan Connor

Completed Status: 18 Oct 2017

Notes:

POR11478 PP1968 Estimated ship to us date changed to / /

Issues:105623

- Back Order Report

POR11500 PP8533 //

Issue ID #107344

Date Created 06/Nov/2017

Issued To: Jonathan Connor

Completed Status: 06 Nov 2017

Notes:

POR11500 PP8533 Estimated ship to us date changed to / /

Issues:107344

- Back Order Report

POR11515 PP1968 //

Issue ID #107690

Date Created 09/Nov/2017

Issued To: Jonathan Connor

Completed Status: 10 Nov 2017

Notes:

POR11515 PP1968 Estimated ship to us date changed to / /

Issues:107690

- Back Order Report

POR11518 PP8050 //

Issue ID #110475

Date Created 15/Dec/2017

Issued To: Jonathan Connor

Completed Status: 15 Dec 2017

Notes:

POR11518 PP8050 Estimated ship to us date changed to / /

Issues:110475

- Back Order Report

POR11518 PP8050 //

Issue ID #110468

Date Created 15/Dec/2017

Issued To: Jonathan Connor

Completed Status: 15 Dec 2017

Notes:

POR11518 PP8050 Estimated ship to us date changed to / /

Issues:110468

- Back Order Report

POR11529 PP8060 //

Issue ID #108706

Date Created 22/Nov/2017

Issued To: Jonathan Connor

Completed Status: 23 Nov 2017

Notes:

POR11529 PP8060 Estimated ship to us date changed to / /

Issues:108706

- Back Order Report

POR11529 PP8065 //

Issue ID #108707

Date Created 22/Nov/2017

Issued To: Jonathan Connor

Completed Status: 23 Nov 2017

Notes:

POR11529 PP8065 Estimated ship to us date changed to / /

Issues:108707

Stock Processing - Stock Processing

Warehouse Request

Issue ID #105107

Date Created 11/Oct/2017

Issued To: Jonathan Connor

Completed Status: 14 Nov 2017

Notes:

Side Port for use with PP8715 Oxygen

11 Oct 2017 Jonathan Connor

Thanks

Issues:105107

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 :

we have ceased selling these devices due to MHRA / BSI regulations and costs

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 :

we have ceased selling these devices due to MHRA / BSI regulations and costs