



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
18 / 01 / 21



VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
-  Countries Review
-  Returns Review
-  Design Changes Review
-  User Instructions Review
-  Labels Review
-  Document Updates Review
-  Internal Issues Review
-  Clinical / FDA Incidents online search

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:

No product changes
all products discontinued

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:

No product changes
all products discontinued
supplier review not required

Sales Information

Stock Reference	Description	2015	2016	2017	2018	2019	2020	2021
PP1968	Connector - 22mm Oxygen	151	16	30		10		
PP8000	Oxygen Hood - Size 1 wi	13	10	9				
PP8000/SF	Sliding Front for use with PP8000/PP8020							
PP8020	Oxygen Hood - Size 1 wi	18	5	2			7	
PP8050	Oxygen Hood - Size 2 wi	16	15	4				
PP8050/SF	Sliding Front for use wi							
PP8055	Oxygen Hood - Size 2 wi	4	10					
PP8060	Oxygen Hood - Size 3 wi	28	25	5	11			
PP8060/SF	Sliding Front for use with PP8060/PP8065							
PP8065	Oxygen Hood - Size 3 wi	7	9	3				
PP8066	Sliding Front Retaining							
PP8509	Phototherapy Light Shiel						3	
PP8533	Phototherapy Light Shiel	22	30	70		50		
PP8540	Phototherapy Light Shield/Oxygen Hood.							
PP8562	Phototherapy Light Shiel	4					1	
PP8565	Phototherapy Light Shield/Oxygen Hood.							
PP8589	Oxygen Hood - Size 4 wi	25	15	3	13		1	
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.							
PP8715	Oxygen Hood - Size 4 wi	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							
PP8772	Oxygen hood - special.							
PP8773	Oxygen hood - special.							
PP8774	Oxygen Hood - special.							

Stock Reference	Description	2015	2016	2017	2018	2019	2020	2021
PP8775	Oxygen Hood - special.							
PP8780	Oxygen Hood - Size 1 without sliding							
PP8781	Oxygen Hood - Size 2 wi							
PP8782	Oxygen Hood - Size 3 wi							
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:

No product changes
all products discontinued

Countries Review

Country	2015	2016	2017	2018	2019	2020	2021
AU Austria							
BA State of Bahrain	[X]						
Belgium	[X]	[X]	[X]				
Bosnia & Herzegovina	[X]						
Channel Islands							
Cyprus	[X]	[X]					
France	[X]	[X]			[X]		
Germany	[X]	[X]	[X]		[X]		
Gibraltar							
GR Greece							
Greece							
Guernsey							
IN India							
Ireland	[X]	[X]					
Italy							
JO Jordan							
Kuwait	[X]						
MAC Macedonia	[X]						
MAU Mauritius		[X]	[X]				
MOL MOLDOVA							
Northern Ireland							
Oman	[X]	[X]	[X]				
Poland							
Portugal	[X]						
Romania	[X]	[X]		[X]			
Scotland							
SP Spain				[X]			
Spain		[X]	[X]				
Sweden							
Switzerland							
TT Trinidad and Tobago							
Turkey							
UAE U A E							
UK	[X]	[X]	[X]				
UK United Kingdom		[X]					
Zambia						[X]	

Comments on Sales to Countries:

No product changes
all products discontinued

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2015	2016	2017	2018	2019	2020	2021
PP8050	Unchecked - Returned To Stock							
PP8055	New							
PP8060	Unchecked - Returned To Stock							
PP8533	No Fault Found							
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:

No product changes
all products discontinued

Comments on Risks with Returns and Potential Re-work:

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No product changes
all products discontinued

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:

No product changes
all products discontinued

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:

No product changes
all products discontinued

Comments on Risks Labels:

Documentation Updates / Changes

Comments on Document Changes:

No product changes
all products discontinued

Comments on Risks with Document Changes:

Internal Issues Review

Number of Issues reviewed: 2

	Subject
	PP8400 Phototherapy Light Shield, Size 1 165 mm (L) x 215 mm (W) x 150 mm (H) (Internal) For use with PP8000 oxygen h
	Web Site Question ID 8172

Comments on Issues:

No product changes
all products discontinued

Comments on Risks with Issues:

VIAMED Stock Meeting - Stock Queries

**PP8400 Phototherapy Light Shield, Size 1
165 mm (L) x 215 mm (W) x 150 mm (H) (I**

Issue ID #204464

Date Created 11/Nov/2020

Issued To: Derek Lamb

Completed Status: 13 Nov 2020

Notes:

Added by Catrin Hird sent to Derek Lamb

I believe this bar code needs to be killed as it could not be found.

12 Nov 2020 Derek Lamb
done

13 Nov 2020 Catrin Hird
Thanks

Issues:204464

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

Web Site Question ID 8172

Issue ID #189356

Date Created 03/Jul/2020

Issued To: Kate Griffiths

Completed Status: 03 Jul 2020

Notes:

Web Site Question ID 8172

03/07/20

stephanie.mchale@nuh.nhs.uk

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

Stephanie McHale

Nottingham Children's Hospital, Nottingham University Hospitals

Children's

stephanie.mchale@nuh.nhs.uk

--

Type: General

Please could you send me prices and availability of your standard oxygen hoods - PP8060, PP8589
And oxygen analysers 0111211 and 0111212

Request further Information on

03 Jul 2020 Kate Griffiths

advised no longer able to supply, attached leaflet.

Issues:189356

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 :

No product changes
all products discontinued

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 product changes
all products discontinued