



VIA MED

Oxygen Tents/Hoods Nova

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 0101

Carried out by Derek Lamb
18 / 11 / 19



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
2310000	Oxygen hood/tent - standard.
2310001	Oxygen hood/tent - standard.
2310002	Oxygen hood/tent - standard.
2310003	Oxygen hood/tent - standard.
2310004	Oxygen hood/tent - standard.
2310005	Oxygen hood/tent - standard.
2310006	Oxygen hood/tent - standard.
2310007	Oxygen hood/tent - standard.
2310008	Oxygen hood/tent - standard.
2310009	Oxygen hood/tent - standard.
2310010	Oxygen hood/tent - standard.
2310011	Oxygen hood/tent - standard.
2310012	Oxygen hood/tent - standard.
2310013	Oxygen hood/tent - standard.
2310014	Oxygen hood/tent - standard.
2310020	Oxygen hood/tent - dual port.
2310021	Oxygen hood/tent - ICN with 3 ports.
2310025	Oxygen hood/tent - no bottom.
2310026	Oxygen hood/tent - no bottom.
2310027	Oxygen hood/tent - no bottom.
2310028	Oxygen hood/tent - no bottom.
2310029	Oxygen hood/tent - no bottom.
2310030	Oxygen hood/tent - no bottom.
2310031	Oxygen hood/tent - no bottom.
2310032	Oxygen hood/tent - no bottom.
2310033	Oxygen hood/tent - no bottom.
2310034	Oxygen hood/tent - no bottom.
2310035	Oxygen hood/tent - no bottom.
2310050	Oxygen hood/tent - partial bottom.
2310051	Oxygen hood/tent - partial bottom.
2310052	Oxygen hood/tent - partial bottom.
2310053	Oxygen hood/tent - partial bottom.
2310054	Oxygen hood/tent - partial bottom.
2310055	Oxygen hood/tent - partial bottom.
2310075	Oxygen hood/tent - NICU.
2310076	Oxygen hood/tent - NICU.
2310077	Oxygen hood/tent - NICU.
2310078	Oxygen hood/tent - NICU.
2310079	Oxygen hood/tent - NICU.
2310080	Oxygen hood/tent - NICU.
2310081	Oxygen hood/tent - NICU.
2310100	Low birth weight tenthouse

Stock Reference	Description
2310101	Low birth weight tenthouse w/port
2310102	Low birth weight tenthouse top access
2310103	Low birth weight tenthouse with top &
2310104	Low birth weight tenthouse
2310105	Low birt weight tenthouse w/port.
2310106	Low birth weight tenthouse top access
2310107	Low birth weight tenthouse with top &
2310125	Double tent set
2310126	Double tent set
2310127	Double tent set
2310128	Double tent set inner no bottom
2310129	Double tent set
2310130	Double tent set
2310131	Double tent - outer tent only for use
2310132	Double tent - outer tent only for use
2310133	Double tent - outer tent only for use
2310134	Double tent - outer tent only for use
2310140	Babyshield - infant heat shield
2310141	Babyshield - infant heat shield with
2310145	Oxygen hood - no drape.
2310150	Isolation canopy - chair.
2310151	Isolation canopy - crib.
2330000	Oxygen hood/tent - standard.
2330001	Oxygen hood/tent - standard.
2330002	Oxygen hood/tent - standard.
2330003	Oxygen hood/tent - standard.
2330004	Oxygen hood/tent - standard.
2330006	Oxygen hood/tent - standard.
2330007	Oxygen hood/tent - standard.
2330010	Oxygen hood/tent - standard.
2330011	Oxygen hood/tent - standard.
2330013	Oxygen hood/tent - standard.
2330014	Oxygen hood/tent - standard.
2330020	Oxygen hood/tent - dual port.
2330021	Oxygen hood/tent - ICN with 3 ports.
2330025	Oxygen hood/tent - no bottom.
2330026	Oxygen hood/tent - no bottom.
2330027	Oxygen hood/tent - no bottom.
2330028	Oxygen hood/tent - no bottom.
2330029	Oxygen hood/tent - no bottom.
2330031	Oxygen hood/tent - no bottom.
2330032	Oxygen hood/tent - no bottom.
2330035	Oxygen hood/tent - no bottom.
2330050	Oxygen hood/tent - partial bottom.
2330052	Oxygen hood/tent - partial bottom.

Stock Reference	Description
2330053	Oxygen hood/tent - partial bottom.
2330055	Oxygen hood/tent - partial bottom.
2330075	Oxygen hood/tent - NICU.
2330076	Oxygen hood/tent - NICU.
2330077	Oxygen hood/tent - NICU.
2330078	Oxygen hood/tent - NICU.
2330080	Oxygen hood/tent - NICU.
2330081	Oxygen hood/tent - NICU.
2330100	Low birthweight tenthouse
2330101	Low birthweight tenthouse w/port
2330103	Low birthweight tenthouse with top &
2330104	Low birthweight tenthouse
2330105	Low birthweight tenthouse w/port.
2330107	Low birthweight tenthouse with top &
2330125	Double tent set
2330126	Double tent set
2330127	Double tent set
2330128	Double tent set inner no bottom
2330129	Double tent set
2330130	Double tent set
2330131	Double tent - outer tent only for use
2330132	Double tent - outer tent only for use
2330133	Double tent - outer tent only for use
2330134	Double tent - outer tent only for use
2330140	Babyshield - infant heat shield
2330141	Babyshield - infant heat shield with
2330500	Label for Oxygen hoods & plastics...
2330501	Label for Oxygen hoods & plastics...

Comments on Stock references review:

part number unchanged, due to no longer selling / producing

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
2310000	Oxygen hood/tent - stand	00012241	903011	Peace Medical (Formaly N	B
2310001	Oxygen hood/tent - stand	00012241	903202	Peace Medical (Formaly N	B
2310002	Oxygen hood/tent - stand	00012241	900800	Peace Medical (Formaly N	B
2310003	Oxygen hood/tent - stand	00012241	903081	Peace Medical (Formaly N	B
2310004	Oxygen hood/tent - stand	00012241	903012	Peace Medical (Formaly N	B
2310006	Oxygen hood/tent - stand	00012241	903213	Peace Medical (Formaly N	B
2310007	Oxygen hood/tent - stand	00012241	903013	Peace Medical (Formaly N	B
2310010	Oxygen hood/tent - stand	00012241	903014	Peace Medical (Formaly N	B
2310011	Oxygen hood/tent - stand	00012241	907011	Peace Medical (Formaly N	B
2310013	Oxygen hood/tent - stand	00012241	903015	Peace Medical (Formaly N	B
2310014	Oxygen hood/tent - stand	00012241	907024	Peace Medical (Formaly N	B
2310020	Oxygen hood/tent - dual	00012241	903022	Peace Medical (Formaly N	B
2310021	Oxygen hood/tent - ICN w	00012241	903092	Peace Medical (Formaly N	B
2310025	Oxygen hood/tent - no bo	00012241	903101	Peace Medical (Formaly N	B
2310026	Oxygen hood/tent - no bo	00012241	903016	Peace Medical (Formaly N	B
2310027	Oxygen hood/tent - no bo	00012241	903201	Peace Medical (Formaly N	B
2310028	Oxygen hood/tent - no bo	00012241	903082	Peace Medical (Formaly N	B
2310029	Oxygen hood/tent - no bo	00012241	903017	Peace Medical (Formaly N	B
2310031	Oxygen hood/tent - no bo	00012241	903214	Peace Medical (Formaly N	B
2310032	Oxygen hood/tent - no bo	00012241	903018	Peace Medical (Formaly N	B
2310035	Oxygen hood/tent - no bo	00012241	903094	Peace Medical (Formaly N	B
2310050	Oxygen hood/tent - parti	00012241	903049	Peace Medical (Formaly N	B
2310052	Oxygen hood/tent - parti	00012241	903019	Peace Medical (Formaly N	B
2310055	Oxygen hood/tent - parti	00012241	903020	Peace Medical (Formaly N	B
2310075	Oxygen hood/tent - NICU.	00012241	903005	Peace Medical (Formaly N	B
2310076	Oxygen hood/tent - NICU.	00012241	903008	Peace Medical (Formaly N	B
2310077	Oxygen hood/tent - NICU.	00012241	903009	Peace Medical (Formaly N	B
2310078	Oxygen hood/tent - NICU.	00012241	903006	Peace Medical (Formaly N	B
2310080	Oxygen hood/tent - NICU.	00012241	903215	Peace Medical (Formaly N	B
2310081	Oxygen hood/tent - NICU.	00012241	903007	Peace Medical (Formaly N	B
2310100	Low birth weight tenthou	00012241	903200	Peace Medical (Formaly N	B
2310104	Low birth weight tenthou	00012241	903301	Peace Medical (Formaly N	B
2310107	Low birth weight tenthou	00012241	903307	Peace Medical (Formaly N	B
2310125	Double tent set	00012241	903028	Peace Medical (Formaly N	B
2310140	Babyshield - infant heat	00012241	909028	Peace Medical (Formaly N	B
2310141	Babyshield - infant heat	00012241	909030	Peace Medical (Formaly N	B

Comments on Suppliers:

part number unchanged, due to no longer selling / producing

Sales Information

Stock Reference	Description	2013	2014	2015	2016	2017	2018	2019
2310000	Oxygen hood/tent - stand	1			4			2
2310001	Oxygen hood/tent - stand	4	6	1	6	2		2
2310002	Oxygen hood/tent - stand						4	
2310003	Oxygen hood/tent - stand	2	2	1	1	1		
2310004	Oxygen hood/tent - stand	5	1	4	4	3	9	
2310005	Oxygen hood/tent - standard.							
2310006	Oxygen hood/tent - stand	9	4				5	
2310007	Oxygen hood/tent - stand	34	18	29	13	13	9	
2310008	Oxygen hood/tent - standard.							
2310009	Oxygen hood/tent - standard.							
2310010	Oxygen hood/tent - stand	51	44	44	35	65		
2310011	Oxygen hood/tent - stand							
2310012	Oxygen hood/tent - standard.							
2310013	Oxygen hood/tent - stand	30	18	23	14	5	3	
2310014	Oxygen hood/tent - stand							
2310020	Oxygen hood/tent - dual							
2310021	Oxygen hood/tent - ICN w							
2310025	Oxygen hood/tent - no bo	1						
2310026	Oxygen hood/tent - no bo		1					
2310027	Oxygen hood/tent - no bo		2					
2310028	Oxygen hood/tent - no bo		2					
2310029	Oxygen hood/tent - no bo	2	6	0	15			
2310030	Oxygen hood/tent - no bottom.							
2310031	Oxygen hood/tent - no bo		2	1	12			
2310032	Oxygen hood/tent - no bo	14	31	8	5	7	12	
2310033	Oxygen hood/tent - no bottom.							
2310034	Oxygen hood/tent - no bottom.							
2310035	Oxygen hood/tent - no bo	37	31	44	30	4	2	26
2310050	Oxygen hood/tent - parti						3	
2310051	Oxygen hood/tent - partial bottom.							
2310052	Oxygen hood/tent - parti	2	1	3				
2310053	Oxygen hood/tent - partial bottom.							
2310054	Oxygen hood/tent - partial bottom.							
2310055	Oxygen hood/tent - parti	2		3				
2310075	Oxygen hood/tent - NICU.							
2310076	Oxygen hood/tent - NICU.							
2310077	Oxygen hood/tent - NICU.							
2310078	Oxygen hood/tent - NICU.							
2310079	Oxygen hood/tent - NICU.							
2310080	Oxygen hood/tent - NICU.							
2310081	Oxygen hood/tent - NICU.							
2310100	Low birth weight tenthou							

Stock Reference	Description	2013	2014	2015	2016	2017	2018	2019
2310101	Low birth weight tenthouse w/port							
2310102	Low birth weight tenthouse top access							
2310103	Low birth weight tenthouse with top &							
2310104	Low birth weight tenthou							1
2310105	Low birt weight tenthouse w/port.							
2310106	Low birth weight tenthouse top access							
2310107	Low birth weight tenthou							1
2310125	Double tent set							
2310126	Double tent set							
2310127	Double tent set							
2310128	Double tent set inner no bottom							
2310129	Double tent set							
2310130	Double tent set							
2310131	Double tent - outer tent only for use							
2310132	Double tent - outer tent only for use							
2310133	Double tent - outer tent only for use							
2310134	Double tent - outer tent only for use							
2310140	Babyshield - infant heat							
2310141	Babyshield - infant heat							1
2310145	Oxygen hood - no drape.							
2310150	Isolation canopy - chair.							
2310151	Isolation canopy - crib.							
2330000	Oxygen hood/tent - standard.							
2330001	Oxygen hood/tent - standard.		1					
2330002	Oxygen hood/tent - standard.							
2330003	Oxygen hood/tent - standard.							
2330004	Oxygen hood/tent - standard.		1					
2330006	Oxygen hood/tent - standard.							
2330007	Oxygen hood/tent - standard.							
2330010	Oxygen hood/tent - standard.		1					
2330011	Oxygen hood/tent - standard.							
2330013	Oxygen hood/tent - standard.		2					
2330014	Oxygen hood/tent - standard.							
2330020	Oxygen hood/tent - dual port.							
2330021	Oxygen hood/tent - ICN with 3 ports.							
2330025	Oxygen hood/tent - no bottom.							
2330026	Oxygen hood/tent - no bottom.							
2330027	Oxygen hood/tent - no bottom.							
2330028	Oxygen hood/tent - no bottom.							
2330029	Oxygen hood/tent - no bottom.							
2330031	Oxygen hood/tent - no bottom.							
2330032	Oxygen hood/tent - no bottom.							
2330035	Oxygen hood/tent - no bottom.		1					
2330050	Oxygen hood/tent - partial bottom.							
2330052	Oxygen hood/tent - partial bottom.							

Stock Reference	Description	2013	2014	2015	2016	2017	2018	2019
2330053	Oxygen hood/tent - partial bottom.							
2330055	Oxygen hood/tent - partial bottom.							
2330075	Oxygen hood/tent - NICU.							
2330076	Oxygen hood/tent - NICU.							
2330077	Oxygen hood/tent - NICU.							
2330078	Oxygen hood/tent - NICU.							
2330080	Oxygen hood/tent - NICU.							
2330081	Oxygen hood/tent - NICU.							
2330100	Low birthweight tenthouse							
2330101	Low birthweight tenthouse w/port							
2330103	Low birthweight tenthouse with top &							
2330104	Low birthweight tenthouse							
2330105	Low birthweight tenthouse w/port.							
2330107	Low birthweight tenthouse with top &							
2330125	Double tent set							
2330126	Double tent set							
2330127	Double tent set							
2330128	Double tent set inner no bottom							
2330129	Double tent set							
2330130	Double tent set							
2330131	Double tent - outer tent only for use							
2330132	Double tent - outer tent only for use							
2330133	Double tent - outer tent only for use							
2330134	Double tent - outer tent only for use							
2330140	Babyshield - infant heat shield							
2330141	Babyshield - infant heat shield with							
2330500	Label for Oxygen hoods & plastics...							
2330501	Label for Oxygen hoods & plastics...							

Comments on Sales Information:

no longer selling / producing

Countries Review

Country	2013	2014	2015	2016	2017	2018	2019
B Belgium		[X]					
F France							
G Germany		[X]					
GR Greece	[X]				[X]		
IRE Ireland	[X]	[X]		[X]	[X]		
IS Israel				[X]			
IT Italy		[X]	[X]				
JO Jordan							
K South Korea			[X]				
NE Netherlands							
P Poland							
RO Romania			[X]				
SP Spain	[X]						
SW Sweden							
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
ZA ZAMBIA							[X]

Comments on Sales to Countries:

no longer selling / producing

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2013	2014	2015	2016	2017	2018	2019
2310000	Unchecked - Returned To Stock							

Comments on Returns:

no longer selling / producing

Comments on Risks with Returns and Potential Re-work:

no longer selling / producing

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no longer selling / producing

Comments on Risks with Design Changes:

no longer selling / producing

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
13626	Oxygen Hoods Instructions for Use User Manual Italian	07/04/14
9084	Nova Oxygen Tents Cleaning Instructions	18/10/11
8969	Nova Oxygen Tents Instructions for Use / User Manual	18/10/11

Comments on User Instructions:

no longer selling / producing

Comments on Risks User Instructions:

no longer selling / producing

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
8977	Nova Oxygen Tents Packaging Trials and validation Handling infor...	18/10/11
8961	Nova Oxygen Tents Accessory Labels List of Accessories	18/10/11
7690	Nova Oxygen Tents Labels	15/02/11

Comments on Labels:

no longer selling / producing

Comments on Risks Labels:

no longer selling / producing

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
29753	Viamed CE Certificate CE01389 Internal Use Only Cancellation Le...	29/05/19
27928	Nova Oxygen Tents Clinical Trials Reports Reviews and Post Marke...	25/10/18

Comments on Document Changes:

no longer selling / producing

Comments on Risks with Document Changes:

no longer selling / producing

Internal Issues Review

Number of Issues reviewed: 2

Issue ID	Subject
135387	Xero Accounts Upgrade Sales Back Orders Review - By Customer Backorder 00001902 2310035 ORD95898
144046	Xero Accounts Upgrade VIAMED Stock Meeting Price Checking (418)

Comments on Issues:

nothing in the issue system

Comments on Risks with Issues:

VIAMED Stock Meeting - Sales Back Orders Review - By Customer

Backorder 00001902 2310035 ORD95898

Issue ID #135387

Date Created 04/Jan/2019

Issued To: Kate Griffiths

Completed Status: 11 Jan 2019

Stock Ref: 2310035

Opera A/c: 00001902

Order Number: ORD95898

Notes:

04 Jan 2019 09:43:54 AM Kate Griffiths
£30 carriage max, asked customer to confirm. KG 4.1.19

10 Jan 2019 11:31:07 AM Kate Griffiths
See Attached Notes
rang and emailed to ask about £30 carriage max. Emailed 3 different email address to chase as 11.1.19
deadline 10.1.19kg

10 Jan 2019 Kate Griffiths
done
11 Jan 2019 07:34:05 AM Catherine Spence
Shipping Fri 11 Jan 2019

11 Jan 2019 Kate Griffiths
done

Issues:135387

VIAMED Stock Meeting - VIAMED Stock Meeting

Price Checking (418)

Issue ID #144046

Date Created 03/May/2019

Issued To: Steve Nixon

Completed Status: 08 May 2019

Notes:

System Generated

Task To be Completed

Check Stock Price Check Page:

Intrastats: Stock - stock analysis - Price Check

Correct Special Price Lists of any Items showing.

03 May 2019 Steve Nixon

Next Action Changed From Steve Nixon To Catrin Hird Just appear to be the disp hoods and Masimo sensors that were being sold off at sales prices. Have you reviewed the stock?

03 May 2019 Catrin Hird

Next Action Changed From Catrin Hird To Steve Nixon All still in stock apart from 2310007 and 2710250 which are showing as discontinued.

07 May 2019 Steve Nixon

As discussed, prices should be edited back when each stock line has been sold off.

Issues:144046

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 longer selling / producing

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 longer selling / producing