



VIA MED

Oxygen Tents/Hoods Nova

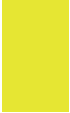
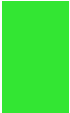
Enclosures to enable oxygen enriched air and humidity to be supplied to the patients head only.

Class IIa
Via Rule Rule 2
Assesment Route Annex II
NBOG MD 0101

Carried out by Derek Lamb
18 / 01 / 21



VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
-  Countries Review
-  Returns Review
-  Design Changes Review
-  User Instructions Review
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-  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:

No product changes
all products discontinued

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:

No product changes
all products discontinued
supplier review not required

Sales Information

Stock Reference	Description	2015	2016	2017	2018	2019	2020	2021
2310000	Oxygen hood/tent - stand		4			2		
2310001	Oxygen hood/tent - stand	1	6	2		2	1	
2310002	Oxygen hood/tent - stand				4			
2310003	Oxygen hood/tent - stand	1	1	1				
2310004	Oxygen hood/tent - stand	4	4	3	9			
2310005	Oxygen hood/tent - standard.							
2310006	Oxygen hood/tent - stand				5			
2310007	Oxygen hood/tent - stand	29	13	13	9			
2310008	Oxygen hood/tent - standard.							
2310009	Oxygen hood/tent - standard.							
2310010	Oxygen hood/tent - stand	44	35	65				
2310011	Oxygen hood/tent - stand							
2310012	Oxygen hood/tent - standard.							
2310013	Oxygen hood/tent - stand	23	14	5	3		2	
2310014	Oxygen hood/tent - stand							
2310020	Oxygen hood/tent - dual							
2310021	Oxygen hood/tent - ICN w							
2310025	Oxygen hood/tent - no bo							
2310026	Oxygen hood/tent - no bo							
2310027	Oxygen hood/tent - no bo							
2310028	Oxygen hood/tent - no bo							
2310029	Oxygen hood/tent - no bo	0	15					
2310030	Oxygen hood/tent - no bottom.							
2310031	Oxygen hood/tent - no bo	1	12					
2310032	Oxygen hood/tent - no bo	8	5	7	12			
2310033	Oxygen hood/tent - no bottom.							
2310034	Oxygen hood/tent - no bottom.							
2310035	Oxygen hood/tent - no bo	44	30	4	2	26		
2310050	Oxygen hood/tent - parti				3			
2310051	Oxygen hood/tent - partial bottom.							
2310052	Oxygen hood/tent - parti	3						
2310053	Oxygen hood/tent - partial bottom.							
2310054	Oxygen hood/tent - partial bottom.							
2310055	Oxygen hood/tent - parti	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.						2	
2310100	Low birth weight tenthou							

Stock Reference	Description	2015	2016	2017	2018	2019	2020	2021
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.							
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	2015	2016	2017	2018	2019	2020	2021
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 product changes
all products discontinued
sales on ebay to non medical customers (gardening)

Countries Review

Country	2015	2016	2017	2018	2019	2020	2021
B Belgium							
France							
G Germany							
Greece			[X]				
Ireland		[X]	[X]				
Italy	[X]						
JO Jordan							
Netherlands							
Poland							
Romania	[X]						
South Korea	[X]						
Spain							
UK	[X]	[X]	[X]	[X]	[X]		
UK United Kingdom							
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
2310000	Unchecked - Returned 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
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 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
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 product changes
all products discontinued

Comments on Risks Labels:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
31686	Nova Oxygen Tents Clinical Trials Reports Reviews and Post Marke...	18/11/19

Comments on Document Changes:

No product changes
all products discontinued

Comments on Risks with Document Changes:

Internal Issues Review

Number of Issues reviewed: 1

Issue ID	Subject
172918	Backorder 00006666 2310081 123223

Comments on Issues:

No product changes
all products discontinued

Comments on Risks with Issues:

- Sales Back Orders Review - By Customer
Backorder 00006666 2310081 123223
Issue ID #172918
Date Created 01/Jan/1970
Issued To:
Completed Status: 08 Apr 2020
Stock Ref: 2310081
Order Number: 123223

Notes:

Issues:172918

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