



VIA MED

Nova Oxygen Tents

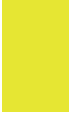
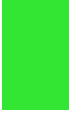
Enclosures to enable oxygen enriched air and humidity to be supplied to the patients head only.

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

Carried out by Derek Lamb
15 / 08 / 16



VIA MED

-  Stock References Review
-  Supplier Review
-  Sales Review
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-  Returns Review
-  Design Changes Review
-  User Instructions Review
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-  Document Updates Review
-  Internal Issues Review
-  Clinical / FDA Incidents online search
-  Risk ISO 14971 : 2012 Review

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 number2 upto dates

Supplier Review

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

Comments on Suppliers:

supplier review upto date

Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
2310000	Oxygen hood/tent - stand	3	3	-3	1			
2310001	Oxygen hood/tent - stand	7		5	4	6	1	
2310002	Oxygen hood/tent - stand	10	4					
2310003	Oxygen hood/tent - stand			1	2	2	1	
2310004	Oxygen hood/tent - stand	12		2	5	1	4	
2310005	Oxygen hood/tent - standard.							
2310006	Oxygen hood/tent - stand	11	20	2	9	4		
2310007	Oxygen hood/tent - stand	60	40	25	34	18	29	8
2310008	Oxygen hood/tent - standard.							
2310009	Oxygen hood/tent - standard.							
2310010	Oxygen hood/tent - stand	82	69	60	51	44	44	17
2310011	Oxygen hood/tent - stand							
2310012	Oxygen hood/tent - standard.							
2310013	Oxygen hood/tent - stand	49	36	28	30	18	23	7
2310014	Oxygen hood/tent - stand	6	8					
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		19		2	6	0	15
2310030	Oxygen hood/tent - no bottom.							
2310031	Oxygen hood/tent - no bo		5	4		2	1	4
2310032	Oxygen hood/tent - no bo	1	30	21	14	31	8	2
2310033	Oxygen hood/tent - no bottom.							
2310034	Oxygen hood/tent - no bottom.							
2310035	Oxygen hood/tent - no bo	9	37	33	37	31	44	5
2310050	Oxygen hood/tent - parti							
2310051	Oxygen hood/tent - partial bottom.							
2310052	Oxygen hood/tent - parti			4	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.	4						
2310077	Oxygen hood/tent - NICU.							
2310078	Oxygen hood/tent - NICU.	4						
2310079	Oxygen hood/tent - NICU.							
2310080	Oxygen hood/tent - NICU.							
2310081	Oxygen hood/tent - NICU.	4						
2310100	Low birth weight tenthou							

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
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							
2310105	Low birt weight tenthouse w/port.							
2310106	Low birth weight tenthouse top access							
2310107	Low birth weight tenthou							
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							
2310145	Oxygen hood - no drape.							
2310150	Isolation canopy - chair.							
2310151	Isolation canopy - crib.							
2330000	Oxygen hood/tent - standard.		1					
2330001	Oxygen hood/tent - standard.	1	1			1		
2330002	Oxygen hood/tent - standard.		3					
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.			1				
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.			1				
2330032	Oxygen hood/tent - no bottom.							
2330035	Oxygen hood/tent - no bottom.			4		1		
2330050	Oxygen hood/tent - partial bottom.							
2330052	Oxygen hood/tent - partial bottom.							

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
2330053	Oxygen hood/tent - partial bottom.							
2330055	Oxygen hood/tent - partial bottom.							
2330075	Oxygen hood/tent - NICU.	1	1					
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:

units still selling

Countries Review

Country	2010	2011	2012	2013	2014	2015	2016
B Belgium	[X]				[X]		
F France							
G Germany					[X]		
GR Greece	[X]			[X]			
IRE Ireland	[X]	[X]	[X]	[X]	[X]		
IS Israel							[X]
IT Italy					[X]	[X]	
JO Jordan							
K Korea						[X]	
NE Netherlands	[X]	[X]					
P Poland		[X]	[X]				
RO Romania						[X]	
SP Spain				[X]			
SW Sweden		[X]					
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

new country Isreal,
Korea
Romainia

Comments on Risks with Sales to Countries:

No risks identified with new countries

Returns Review

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
2310000	Unchecked - Returned to Stock							

Comments on Returns:

Zero failures, just a return to stock

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 design changes

Comments on Risks with Design Changes:

n/a

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 changes to user instructions

Comments on Risks User Instructions:

n/a

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 changes to labelling

Comments on Risks Labels:

n/a

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
16370	Nova Oxygen Tents EC Declaration of Conformance	24/02/16
15708	Nova Oxygen Tents Compatibility Trials copatibility	22/09/15
15707	Nova Oxygen Tents Full inspection and test Final inspection	22/09/15
15706	Nova Oxygen Tents Test Reports Test reports	22/09/15
15705	Nova Oxygen Tents Purchases purchases	22/09/15
15704	Nova Oxygen Tents Design Reviews QC24 Design review	22/09/15
15703	Nova Oxygen Tents Validation validation	22/09/15
15702	Nova Oxygen Tents Software software	22/09/15
15701	Nova Oxygen Tents Drawings working drawings	22/09/15
15700	Nova Oxygen Tents Preliminary drawings and images preliminary dr...	22/09/15
15699	Nova Oxygen Tents Project Progress QC25 progress reports	22/09/15
15698	Nova Oxygen Tents Work Logs Time scales	22/09/15
15697	Nova Oxygen Tents Design Input Device Design Theory Calculation...	22/09/15
15696	Nova Oxygen Tents Specification Brief Design specs	21/09/15
15695	Nova Oxygen Tents Expected Life of Products signed by Nova	21/09/15
15694	Nova Oxygen Tents OES (OEM) Specifications Nova oxygen tent	21/09/15
15670	Single Patient Use Oxygen Hoods Leaflet (email)	18/09/15
15426	Nova Oxygen Tents Risk analysis reports	11/08/15
15418	PPE Equipment	11/08/15
15183	No risks disposal	21/07/15
15170	Nova Oxygen Tents Clinical Trials Reports Reviews and Post Marke...	16/07/15

Comments on Document Changes:

added scans of some old paper files

Comments on Risks with Document Changes:

no risks identified in the new documentations

Internal Issues Review

Number of Issues reviewed: 25

Issue ID	Subject
72884	Backorder 00000055 2310013 ORD80783
64690	Backorder 00000092 2310035 ORD77072
72715	Backorder 00000290 2310010 ORD80720
74878	Backorder 00000290 2310013 ORD81298
64639	Backorder 00000950 2310032 ORD77062
65057	Backorder 00000950 2310032 ORD77298
65977	Backorder 00000950 2310032 ORD77887
71130	Backorder 00000950 2310032 ORD80151
65099	Backorder 00000950 2310035 ORD77319
65859	Backorder 00000950 2310035 ORD77814
67057	Backorder 00001415 2310031 ORD78512
65053	Backorder 00001902 2310007 ORD77285
65399	Backorder 00001902 2310007 ORD77489
65450	Backorder 00001902 2310007 ORD77519
69083	Backorder 00001902 2310010 ORD79435
65460	Backorder 00002960 2310035 ORD77538
63420	Backorder 00004200 2310013 ORD76375
65122	Backorder 00004200 2310013 ORD77331
63418	Backorder 00005250 2310052 ORD76368
65781	Backorder 00006304 2310007 ORD77721
66445	Backorder 00006315 2310029 ORD78091
13933	Hotel Chennai - Radisson GRT Chennai
61711	Oxygen Hoods to dispose of
60907	Web Site Question ID 519
60906	Web Site Question ID 519

Comments on Issues:

mainly shipping issues / orders

Comments on Risks with Issues:

no risks found in the issues system

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 :

Oxygen Tent, no clinical trial data found - too basic an item.
Nothing to show its out of date.

<https://www.drugs.com/cg/oxygen-tent.html>

https://en.wikipedia.org/wiki/Oxygen_tent

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 :

Oxygen Tent, no FDA reports found
Nothing to show its out of date