



VIA MED

Oxygen Hoods

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 / 08 / 16



VIA MED

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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:

stock reference correct.

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

Comments on Suppliers:

supplier review up to date

Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
PP1968	Connector - 22mm Oxygen	89	161	48	172	35	151	
PP8000	Oxygen Hood - Size 1 wi	30	9	14	9	38	13	
PP8000/SF	Sliding Front for use with PP8000/PP8020							
PP8020	Oxygen Hood - Size 1 wi	2	8		1	13	18	5
PP8050	Oxygen Hood - Size 2 wi	8	15	98	8	39	16	
PP8050/SF	Sliding Front for use wi				1			
PP8055	Oxygen Hood - Size 2 wi	1	8	1	12	7	4	6
PP8060	Oxygen Hood - Size 3 wi	13	18	27	21	22	28	7
PP8060/SF	Sliding Front for use with PP8060/PP8065							
PP8065	Oxygen Hood - Size 3 wi	12	6	14	9	8	7	3
PP8066	Sliding Front Retaining		1		2	2		
PP8509	Phototherapy Light Shiel	17	1		1			
PP8533	Phototherapy Light Shiel	1	-1		20	81	22	30
PP8540	Phototherapy Light Shield/Oxygen Hood.							
PP8562	Phototherapy Light Shiel			1			4	
PP8565	Phototherapy Light Shield/Oxygen Hood.							
PP8589	Oxygen Hood - Size 4 wi	44	14	24	33	30	25	4
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.	6		2				
PP8715	Oxygen Hood - Size 4 wi	13	15	2	12	7	4	
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	6	22		3	3		
PP8772	Oxygen hood - special.							
PP8773	Oxygen hood - special.							
PP8774	Oxygen Hood - special.		1	2				

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
PP8775	Oxygen Hood - special.		1					
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:

units still selling

Countries Review

Country	2010	2011	2012	2013	2014	2015	2016
AU Austria					[X]		
B Belgium	[X]	[X]	[X]	[X]	[X]	[X]	[X]
BA State of Bahrain			[X]			[X]	
BO Bosnia						[X]	
CHA Channel Islands							
CY Cyprus						[X]	[X]
EC Ecuador					[X]		
F France			[X]			[X]	
GI Gibraltar				[X]			
GR Greece	[X]				[X]		
IN India				[X]			
IRE Ireland		[X]	[X]	[X]	[X]	[X]	[X]
IT Italy							
JO Jordan							
KU Kuwait						[X]	
MA Malaysia							
MAC Macedonia				[X]		[X]	
MAU Mauritius	[X]	[X]					
MO Morrocco		[X]					
MOL MOLDOVA				[X]	[X]		
NE Netherlands	[X]						
OM Oman	[X]	[X]	[X]	[X]	[X]	[X]	[X]
P Poland	[X]	[X]		[X]			
PO Portugal						[X]	
Q Qatar			[X]				
RO Romania	[X]					[X]	[X]
RU Russia				[X]	[X]	[X]	[X]
SP Spain	[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]	[X]
YE Yemen					[X]		

Comments on Sales to Countries:

Still selling units world wide

BO Bosnia, KU Kuwait New countries

Comments on Risks with Sales to Countries:

no risks with selling to new countries.

Returns Review

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
PP8050	Unchecked - Returned to Stock							
PP8060	Unchecked - Returned to Stock							
PP8533	No Fault Found					1		
PP8589	Unable to repair				1			
PP8715	Unchecked - Returned to Stock							
PP8757	No Fault Return to Stock							
PP8758	No Fault Return to Stock							

Comments on Returns:

no returns last few years.

Comments on Risks with Returns and Potential Re-work:

no risks with returns

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
14778	Oxygen Hoods Instructions for Use User Manual	19/02/15

Comments on User Instructions:

no changes to the IFU

Comments on Risks User Instructions:

n/a

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:

added handel with care label to outer packaging

Comments on Risks Labels:

no risk identified with labelling

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
16792	Head Box Oxygen Hoods Labels	20/04/16
16403	Oxygen Hoods Residual Risks - Risk assesment	01/03/16
16369	Oxygen Hoods EC Declaration of Conformance	24/02/16
15669	Oxygen Hoods and Phototherapy Leaflet (email)	18/09/15
15617	Heat Shields Packaging Trials and validation 2015 Returned	09/09/15
15616	Heat Shields Packaging Trials and validation 2015 Shipping Out	09/09/15
15615	Heat Shields Packaging Trials and validation 2015 Packaging	09/09/15
15614	Heat Shields Packaging Trials and validation 2015	09/09/15
15183	No risks disposal	21/07/15
15169	Oxygen Hoods Clinical Trials Reports Reviews and Post Market Sur...	16/07/15

Comments on Document Changes:

added packaging trials and tests

Comments on Risks with Document Changes:

no risks identifird with documentations

Internal Issues Review

Number of Issues reviewed: 59

Issue ID	Subject
7687	
9996	
66762	Backorder 00000454 PP8060 ORD78276
64343	Backorder 00000680 PP8589 ORD76929
74950	Backorder 00002320 PP8055 ORD81322
75003	Backorder 00002320 PP8055 ORD81324
74996	Backorder 00002320 PP8065 ORD81324
61640	Backorder 00002600 PP8562 ORD75511
75236	Backorder 00006022 PP8000 ORD81383
61883	Backorder 00006042 PP8065 ORD75578
64398	Backorder 00006070 PP1968 ORD76948
61692	Backorder 00007009 PP8791 ORD75514
62856	Backorder 00007020 PP8020 ORD76091
66981	Backorder 00007020 PP8020 ORD78452
64040	Backorder 00007020 PP8055 ORD76787
66980	Backorder 00007020 PP8055 ORD78452
64777	Backorder 00007033 PP8000 ORD77116
66400	Backorder 00007273 PP8533 ORD78072
75737	Backorder 00007374 PP8065 ORD81531
15170	Can this be completed? Were they credited?
17402	Can you please clear these.
63023	Intersurgical connectors for technical files
61171	New part number required
67826	Oxygen Hoods - Declaration of Conformity
61510	Oxygen hoods to order
16175	Part for stock 1 x PP8589/SF
16176	Parts for stock 4 x PP8066
70489	POR10718 PP8020 //
70487	POR10718 PP8020 //
71440	POR10736 PP8589 //
71165	POR10736 PP8589 //
72518	POR10784 PP8000 //
72519	POR10784 PP8020 //
73155	POR10793 PP8533 //
73152	POR10793 PP8533 //
73156	POR10793 PP8589 //
73153	POR10793 PP8589 //
75149	POR10842 PP8055 //
75138	POR10842 PP8055 //
75150	POR10842 PP8065 //
75139	POR10842 PP8065 //
75251	POR10848 PP8000 //

Issue ID	Subject
75252	POR10848 PP8050 //
75253	POR10848 PP8060 //
75254	POR10849 PP8000 //
75248	POR10849 PP8000 //
75255	POR10849 PP8050 //
75249	POR10849 PP8050 //
75256	POR10849 PP8060 //
75250	POR10849 PP8060 //
76002	POR10875 PP8065 //
76220	POR10879 PP8060 //
76221	POR10879 PP8589 //
63680	Reserve
63021	Return to stock
63020	Return to stock
15528	Tanda back orders
15527	Tanda back orders
65692	Web Site Question ID 770

Comments on Issues:

no problems found in the issue system

Comments on Risks with Issues:

no risks identified in the issue 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 :

non relevant finds :

<http://search.proquest.com/openview/16c885f0f631dc6e38e3f857b0da0881/1?pq-origsite=gscholar>

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 :

See Issue #77144,

hoods being cleaned incorrectly, while not an FDA report as such. it was found while looking.