



VIA MED

Oxygen Tents/Hoods Tanda

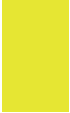
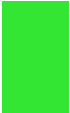
Enclosures to enable oxygen enriched air and humidity
to be supplied to the patients head only

Class IIa
Via Rule Rule 2
Assesment Route Annex II
NBOG MD 0100

Carried out by Derek Lamb
02 / 04 / 24



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:

Part numbers upto date

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

Comments on Suppliers:

no changes to supplier

Sales Information

Stock Reference	Description	2018	2019	2020	2021	2022	2023	2024
PP1968	Connector - 22mm Oxygen		10					
PP8000	Oxygen Hood - Size 1 wi							
PP8000/SF	Sliding Front for use with PP8000/PP8020							
PP8020	Oxygen Hood - Size 1 wi							
PP8050	Oxygen Hood - Size 2 wi							
PP8050/SF	Sliding Front for use wi							
PP8055	Oxygen Hood - Size 2 wi							
PP8060	Oxygen Hood - Size 3 wi	11						
PP8060/SF	Sliding Front for use with PP8060/PP8065							
PP8065	Oxygen Hood - Size 3 wi							
PP8066	Sliding Front Retaining							
PP8509	Phototherapy Light Shiel							
PP8533	Phototherapy Light Shiel		50				150	
PP8540	Phototherapy Light Shield/Oxygen Hood.							
PP8562	Phototherapy Light Shiel							
PP8565	Phototherapy Light Shield/Oxygen Hood.							
PP8589	Oxygen Hood - Size 4 wi	13						
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							
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	2018	2019	2020	2021	2022	2023	2024
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							

Comments on Sales Information:

sold strickly with no ce mark, made clear pre, post sale and on all paperwork,

Countries Review

Country	2018	2019	2020	2021	2022	2023	2024
AU Austria							
BA State of Bahrain							
Belgium							
Bosnia & Herzegovina							
Channel Islands							
Cyprus							
France		[X]					
Germany		[X]				[X]	
Gibraltar							
GR Greece							
Greece							
Guernsey							
IN India							
Italy							
Jordan							
Kuwait							
MAC Macedonia							
MAU Mauritius							
MOL MOLDOVA							
Northern Ireland							
Oman							
Poland							
Portugal							
Romania	[X]						
Russia						[X]	
Scotland							
SP Spain	[X]						
Spain							
Sweden							
Switzerland							
TT Trinidad and Tobago							
Turkey							
UAE U A E							
UK							
UK United Kingdom							

Comments on Sales to Countries:

no issues with countries

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2018	2019	2020	2021	2022	2023	2024
PP8050	Unchecked - Returned To Stock							
PP8055	New							
PP8060	Unchecked - Returned To Stock							
PP8533	No Fault Found							
PP8533	Unchecked - Returned To Stock							
PP8589	Hair Line Crack							
PP8715	New							
PP8715	Unchecked - Returned To Stock							
PP8757	No Fault Return To Stock							
PP8758	No Fault Return To Stock							

Comments on Returns:

no returns

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:

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 updates to manuals

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 changes to labels

Comments on Risks Labels:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
114789	Oxygen Hoods Clinical Trials Reports Reviews and Post Market Sur...	28/03/23

Comments on Document Changes:

no new documentation

Comments on Risks with Document Changes:

Internal Issues Review

Number of Issues reviewed: 1

Issue ID	Subject
148731	Leaflet Leaflet/Catalogue: Lead-free sensors Queries

Comments on Issues:

nothing in the issue system

Comments on Risks with Issues:

Marketing Job Logger - Marketing Job Logger

Leaflet Leaflet/Catalogue: Lead-free sensors Queries

Issue ID #148731

Date Created 03/Jul/2019

Issued To: Steve Nixon

Completed Status: 02 Apr 2024

Linked Files

20 Aug 2019 Oxygen Monitoring Catalogue 2019-08 WIP

Notes:

Catrin Hird 03/07/2019 Issue Generated
Leaflet Leaflet/Catalogue: Lead-free sensors Queries

03 Jul 2019 Catrin Hird

Next Action Changed From To Steve Nixon Please can you confirm the following:

Output for:

R-23V

R-23Vi

R-43V

R-47V

Warranty for 0111002 UFO 130-2 PCB

Do we have compatibility information yet for the ITG LF sensors?

What are the pack quantities we are allowed to sell the t pieces etc in as need to include in the catalogue.

03 Jul 2019 Catrin Hird

Last query is on issue 147122

20 Aug 2019 Catrin Hird

Query for notes given - Page 20, OOM 102 should be OOMLF102 - can not see this? Page 20 is itg.

We do have a spare page available but due to the layout it would not work to have benefits of Lead-free at the front as it would make all following pages out of sync. I have left them as is for now with a blank page at the back - see what you think.

Once happy I will go through full checking again and provide to SJH for proofing.

Notes from SN completed:

0111002 12 months warranty

R-23 & R-23Vi 24-32 uA

R-43V 25-38 mV

R-47V 9-13.5 (2 channels)- remove output difference statement.

Page 22, add MOX-20 Resmed Elisee, 0110707 MLF-60HC 410040

Standard T adapter blue changed to 0120399

PP1968 changed to 0120124

Quantities:

0120092 - 1

0120093 - 10

0120399 - 5
0120124 - 1
0120174 - 50
0120175 - 35
0120176 - 40
0120177 - 45
0120178 - 50
0120179 - 35

Updated text to page 38 for flowsensors - due to space I have been able to put this back to a full page on Flow sensors.

Front cover - added Autumn 2019

Removed -

0120104
0120108
0120109
0121205
T adapter external T 15-22
Perfusion circuit
0120164
0120165
0120166
0120130
0120131
0120133

Hard copy provided with "Information/Amends Sheet"

Issues:148731

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 :

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 :