



VIA MED

Oxygen Tents/Hoods Tanda

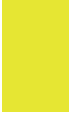
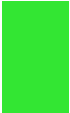
Enclosures to enable oxygen enriched air and humidity
to be supplied to the patients head only

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

Carried out by Derek Lamb
02 / 04 / 25



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:

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

Comments on Suppliers:

Sales Information

Stock Reference	Description	2019	2020	2021	2022	2023	2024	2025
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							
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							
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	2019	2020	2021	2022	2023	2024	2025
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:

Countries Review

Country	2019	2020	2021	2022	2023	2024	2025
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							
Russia					[X]		
Scotland							
SP Spain							
Spain							
Sweden							
Switzerland							
TT Trinidad and Tobago							
Turkey							
UAE U A E							
UK							
UK United Kingdom							

Comments on Sales to Countries:

Comments on Risks with Sales to Countries:

Returns and Q.A. Fails Review

Stock Reference	Fault	2019	2020	2021	2022	2023	2024	2025
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:

Comments on Risks with Returns and Potential Re-work:

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on 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:

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:

Comments on Risks Labels:

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
146785	Oxygen Hoods Clinical Trials Reports Reviews and Post Market Sur...	02/04/24

Comments on Document Changes:

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:

No extra informtion in this file for the last few years time to stop the annual review and reflag as old product.

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 2025

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 :

Do any of the Results indicate outdated Technology :

Comments on Clinical Search :

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem :

Do any of the Results indicate outdated Technology :

Comments on Clinical Search :