



VIAMED

VM-2400 Hb Monitor



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
-  Risk ISO 14971 : 2012 Review

Stock References Review

Stock Reference	Description
0012400	Hb Monitor Viamed VM-2400.
0012405	Hb Sensor for use with Viamed VM-2400.
4421504	Standard Gas Sampling Line - S Type
4421507	Standard Gas Sampling Line - S Type
4421513	Standard Gas Sampling Line - H Type
4421523	Standard Gas Sampling Line - H Type
4421533	Standard Gas Sampling Line - H Type

Comments on Stock references review:

Part numbers upto date

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0012400	Hb Monitor Viamed VM-24	00009300		Bluepoint Medical	A

Comments on Suppliers:

supplier review upto date

Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
0012400	Hb Monitor Viamed VM-24							
0012405	Hb Sensor for use with Viamed VM-2400.							
4421504	Standard Gas Sampling Line - S Type							
4421507	Standard Gas Sampling Line - S Type							
4421513	Standard Gas Sampling Line - H Type							
4421523	Standard Gas Sampling Line - H Type							
4421533	Standard Gas Sampling Line - H Type							

Comments on Sales Information:

No Sales yet

Countries Review

Comments on Sales to Countries:

N/a

Comments on Risks with Sales to Countries:

N/a

Returns Review

Comments on Returns:

N/a

Comments on Risks with Returns and Potential Re-work:

N/a

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

N/a

Comments on Risks with Design Changes:

N/a

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Comments on User Instructions:

N/a

Comments on Risks User Instructions:

N/a

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
15817	VM-2400 Hb Monitor Labels VM-2400 sensor lens	15/10/15
15816	VM-2400 Hb Monitor Labels OxyTrue Hb lens	15/10/15
15815	VM-2400 Hb Monitor Labels OxyTrue® Hb	15/10/15

Comments on Labels:

fit for purpose

Comments on Risks Labels:

no risks identified with labels

Documentation Updates / Changes

Comments on Document Changes:

New product not all documentation in place yet

Comments on Risks with Document Changes:

no risks identified with documentation

Internal Issues Review

Number of Issues reviewed: 22

Issue ID	Subject
66381	0012400 Evaluation of various methods of point-of-care testing of haemoglobin concentration in blood donors
65541	Backorder 00007592 0012400 ORD77578
65924	DOCs required
63691	Hb Monitor VM-2400
65850	Sampling line part numbers - H & S singles
64798	VM-2400 demo units
64797	VM-2400 demo units
64727	VM-2400 demo units
64726	VM-2400 demo units
64725	VM-2400 demo units
64724	VM-2400 demo units
64723	VM-2400 demo units
64722	VM-2400 demo units
64721	VM-2400 demo units
64720	VM-2400 demo units
64719	VM-2400 demo units
64718	VM-2400 demo units
64717	VM-2400 demo units
64716	VM-2400 demo units
65525	VM-2400 Haemoglobin Monitor Write Letter
63729	VM-2400 HB Monitor
64711	VM-2400 marketing

Comments on Issues:

issues on pricing and demo models,
no units sold in the market yet

Comments on Risks with Issues:

no risks identified 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 :

Not out in the market yet

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 :

Not out in the market yet