



VIA MED

Pulse Oximeter VM2101 Finger SpO₂

Finger oximeter for monitoring of functional arterial oxygen saturation (SpO₂) and pulse rate,

Class IIb

NBOG MD1302

Carried out by Derek Lamb
16 / 09 / 14



VIA MED

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Stock References Review

Stock Reference	Description
0012101	Finger Pulse Oximeter Viamed VM 2101.
0012102	Finger Pulse Oximeter Viamed VM 2101.

Comments on Stock references review:

part number correct

Supplier Review

Stock Reference	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0012101	Finger Pulse Oximeter Viamed VM 2101.	00009300	2020112002	Bluepoint Medical	A

Comments on Suppliers:

suppleir review is upto date

Sales Information

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
0012101	Finger Pulse Oximeter Viamed VM 2101.	255	1723	1013	655	671	574	470
0012102	Finger Pulse Oximeter Viamed VM 2101.		2456	1				

Comments on Sales Information:

Units still selling

Countries Review

Country	2008	2009	2010	2011	2012	2013	2014
AU Austria	[X]	[X]				[X]	
B Belgium	[X]	[X]	[X]	[X]	[X]		[X]
CAN Canada		[X]					
CI Canary Islands				[X]	[X]		
CRO Croatia	[X]						
CY Cyprus				[X]			[X]
CZ Czech Republic	[X]			[X]	[X]	[X]	[X]
DE Denmark	[X]						
EG Egypt		[X]		[X]			
ES Estonia		[X]	[X]	[X]	[X]	[X]	
F France				[X]	[X]	[X]	[X]
FI Finland		[X]	[X]	[X]	[X]	[X]	[X]
G Germany	[X]	[X]		[X]			
GEO Georgia			[X]				
GR Greece	[X]	[X]	[X]	[X]		[X]	
I Iran	[X]	[X]	[X]	[X]	[X]	[X]	
IN India	[X]	[X]	[X]	[X]			
IQ IRAQ					[X]	[X]	
IRE Ireland	[X]						
JO Jordan		[X]					
KE Kenya	[X]	[X]	[X]				
KU Kuwait		[X]		[X]			[X]
LEB Lebanon		[X]			[X]		
LI Lithuania					[X]		
MA Malaysia	[X]	[X]			[X]		
NE Netherlands		[X]					
NO Norway		[X]	[X]	[X]	[X]	[X]	[X]
OM Oman		[X]	[X]	[X]	[X]	[X]	[X]
P Poland		[X]	[X]	[X]	[X]	[X]	[X]
PO Portugal	[X]	[X]	[X]				
RO Romania		[X]	[X]				[X]
SAU Saudi Arabia		[X]					
SI Singapore		[X]					
SP Spain		[X]	[X]				[X]
SW Sweden				[X]			[X]
SWI Switzerland	[X]		[X]	[X]	[X]		[X]
T Turkey	[X]						
TH Thailand		[X]					
UAE U A E		[X]	[X]			[X]	[X]
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
USA USA		[X]			[X]		

Comments on Sales to Countries:

No new countries

Comments on Risks with Sales to Countries:

n/a

Returns Review

Stock Reference	Fault	2008	2009	2010	2011	2012	2013	2014
0012101	Dead			3	2		4	
0012101	Display fault		1	3	5	2	1	1
0012101	False reading			3	5	4	1	
0012101	Faulty probe					1		
0012101	High reading				1			
0012101	Intermittent		1					
0012101	No Fault Found			3	1	1		
0012101	No Fault Return to Stock		2					
0012101	PCB damaged			1				
0012101	Picking up false signal		1					
0012101	Rewired		2	1	1			
0012101	Spings missing/detached					1		
0012101	Spring missing			5	5			
0012101	TEST	1		7				
0012101	Unchecked - Returned to Stock							
0012101	Uneconomical to repair						2	
0012101	Unit dead		1		1			
0012101	Unrepaired		1					
0012102	Display fault			2				
0012102	Picking up false signal		6					
0012102	Spring missing			1				

Comments on Returns:

Very Low return rate 0.21% so far in 2014

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 Files held off-site OEM company

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
5078	VM-2101 Finger Oximeter Quick Start Guide	17/02/09
4744	VM-2101 User Instructions German	13/10/08
4743	VM-2101 User Instructions Spanish	13/10/08
4741	VM-2101 User Instructions French	13/10/08
4740	VM-2101 User Instructions English	13/10/08

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
4676	Pulse Oximeter VM2101 Finger SpO2 Labels tracking label	12/09/08
4675	Pulse Oximeter VM2101 Finger SpO2 Labels rear label	12/09/08
4674	Pulse Oximeter VM2101 Finger SpO2 Labels box label - rear	12/09/08
4673	Pulse Oximeter VM2101 Finger SpO2 Labels box labe - side	12/09/08

Comments on Labels:

No changes to Labels

Comments on Risks Labels:

n/a

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
14041	Pulse Oximeter VM2101 Finger SpO2 External Test Results drop tes...	09/06/14
13168	CE 540537 Certificate Customer Copy	22/11/13
13136	Generic CE File Attached to All Medicinal Substances None	31/10/13
13135	No Animal Tissues No Animal Substances	31/10/13
13058	0012101 VM-2101 Finger Oximeter Leaflet (email)	14/10/13
12813	Pulse Oximeter VM2101 Finger SpO2 Clinical Trials Reports Review...	30/07/13

Comments on Document Changes:

Added drop test certificate, no other documents of note.

Comments on Risks with Document Changes:

no risks identified

Internal Issues Review

Number of Issues reviewed: 29

Issue ID	Subject
51371	Returned Items SOR599
51745	Extra information fields
48780	GHX exptrter price break pricing errors
44817	Group Peto Group - Export
40331	Alternative products
46241	GHX/Peto exporter - image links
52016	Auto move QA items to stock shelf
44135	Document Update Request
47814	Ingress Protection Rating - Water Ingress
47813	Ingress Protection Rating - Water Ingress
47812	Ingress Protection Rating - Water Ingress
47811	Ingress Protection Rating - Water Ingress
47810	Ingress Protection Rating - Water Ingress
47809	Ingress Protection Rating - Water Ingress
47808	Ingress Protection Rating - Water Ingress
47807	Ingress Protection Rating - Water Ingress
47806	Ingress Protection Rating - Water Ingress
47805	Ingress Protection Rating - Water Ingress
47804	Ingress Protection Rating - Water Ingress
47803	Ingress Protection Rating - Water Ingress
47802	Ingress Protection Rating - Water Ingress
47800	Ingress Protection Rating - Water Ingress
47799	IPXX Ratings - Ingress Protection
47798	IPXX Ratings - Ingress Protection
47797	IPXX Ratings - Ingress Protection
44249	0012101 VM-2101 IP rating
51649	0012101 & 0012175 stock levels
50479	Drop tests: 0012101, 0012103, 0012105, 0012106
51985	Finger Oximeters - R.H. Specification Update

Comments on Issues:

Mainly sales issues,
one issue requesting drop test data, certificate added to the files)

Comments on Risks with Issues:

no risks identified in 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 :

Pulse oximetry is globally used technology is current and upto date

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 :

Risk ISO 14971 : 2012 Review

Full ISO 14971 : 2012 Risk review held off-site at original OEM company