



VIA MED

Temperature Probes BPM

Reusable Temperature Probe

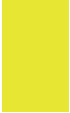
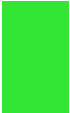
Class IIa

NBOG MD0101

Carried out by Derek Lamb
16 / 09 / 14



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
0212009	Temperature probe - Oesophageal/Rectal.
0212010	Temperature probe - Oesophageal/Rectal.
0212011	Temperature probe - Oesophageal/Rectal.
0212012	Temperature probe - Oesophageal/Rectal.
0212013	Temperature probe - Oesophageal/Rectal.
0212014	Temperature probe - Oesophageal/Rectal.
0212015	Temperature probe - Oesophageal/Rectal.
0212016	Temperature probe - Oesophageal/Rectal.
0212017	Temperature probe - Oesophageal/Rectal.
0212018	Temperature probe - Oesophageal/Rectal.
0212019	Temperature probe - Oesophageal/Rectal.
0212020	Temperature probe - Oesophageal/Rectal.
0212021	Temperature probe - Skin contact.
0212022	Temperature probe - Skin contact.
0212023	Temperature probe - Skin contact.
0212024	Temperature probe - Skin contact.
0212025	Temperature probe - Skin contact.
0212026	Temperature probe - Skin contact.
0212027	Temperature probe - Skin contact.
0212028	Temperature probe - Skin contact.
0212029	Temperature probe - Skin contact.
0212030	Temperature probe - Skin contact.
0212031	Temperature probe - Skin contact.
0212032	Temperature probe - Skin contact.
0222000	Temperature probe - Series 400-AC
0222001	Temperature probe - Series 400-AC

Comments on Stock references review:

Part numbers upto date for review

Supplier Review

Stock Reference	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0212009	Temperature probe - Oesophageal/Rectal.	00009300	TRRE 01-00-2009	Bluepoint Medical	A
0212010	Temperature probe - Oesophageal/Rectal.	00009300	TRRE 01-00-2010	Bluepoint Medical	A
0212011	Temperature probe - Oesophageal/Rectal.	00009300	TRRE 01-00-2011	Bluepoint Medical	A
0212012	Temperature probe - Oesophageal/Rectal.	00009300	TRRE 01-00-2012	Bluepoint Medical	A
0212013	Temperature probe - Oesophageal/Rectal.	00009300	TRRE 01-00-2013	Bluepoint Medical	A
0212014	Temperature probe - Oesophageal/Rectal.	00009300	TRRE 01-00-2014	Bluepoint Medical	A
0212015	Temperature probe - Oesophageal/Rectal.	00009300	TRRE 01-00-2015	Bluepoint Medical	A
0212016	Temperature probe - Oesophageal/Rectal.	00009300	TRRE 01-00-2016	Bluepoint Medical	A
0212017	Temperature probe - Oesophageal/Rectal.	00009300	TRRE 01-00-2017	Bluepoint Medical	A
0212018	Temperature probe - Oesophageal/Rectal.	00009300	TRRE 01-00-2018	Bluepoint Medical	A
0212019	Temperature probe - Oesophageal/Rectal.	00009300	TRRE 01-00-2019	Bluepoint Medical	A
0212020	Temperature probe - Oesophageal/Rectal.	00009300	TRRE 01-00-2020	Bluepoint Medical	A
0212021	Temperature probe - Skin contact.	00009300	TRRE 01-00-2021	Bluepoint Medical	A
0212022	Temperature probe - Skin contact.	00009300	TRSC 01-00-2022	Bluepoint Medical	A
0212023	Temperature probe - Skin contact.	00009300	TRSC 01-00-2023	Bluepoint Medical	A
0212024	Temperature probe - Skin contact.	00009300	TRRE 01-00-2024	Bluepoint Medical	A
0212025	Temperature probe - Skin contact.	00009300	TRRE 01-00-2025	Bluepoint Medical	A
0212026	Temperature probe - Skin contact.	00009300	TRRE 01-00-2026	Bluepoint Medical	A
0212027	Temperature probe - Skin contact.	00009300	TRRE 01-00-2027	Bluepoint Medical	A
0212028	Temperature probe - Skin contact.	00009300	TRRE 01-00-2028	Bluepoint Medical	A
0212029	Temperature probe - Skin contact.	00009300	TRRE 01-00-2029	Bluepoint Medical	A
0212030	Temperature probe - Skin contact.	00009300	TRSC 01-00-2030	Bluepoint Medical	A
0212031	Temperature probe - Skin contact.	00009300	TRRE 01-00-2031	Bluepoint Medical	A
0212032	Temperature probe - Skin contact.	00009300	TRRE 01-00-2032	Bluepoint Medical	A
0222000	Temperature probe - Series 400-AC	00009300	011-00053	Bluepoint Medical	A
0222001	Temperature probe - Series 400-AC	00009300	011-00052	Bluepoint Medical	A

Comments on Suppliers:

supplier review upto date

Sales Information

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
0212009	Temperature probe - Oesophageal/Rectal.	11		6	1		2	
0212010	Temperature probe - Oesophageal/Rectal.	10		2	5		2	
0212011	Temperature probe - Oesophageal/Rectal.	11			1		2	9
0212012	Temperature probe - Oesophageal/Rectal.	1						
0212013	Temperature probe - Oesophageal/Rectal.	4						
0212014	Temperature probe - Oesophageal/Rectal.	4	1		5			
0212015	Temperature probe - Oesophageal/Rectal.							
0212016	Temperature probe - Oesophageal/Rectal.							
0212017	Temperature probe - Oesophageal/Rectal.	5						
0212018	Temperature probe - Oesophageal/Rectal.							3
0212019	Temperature probe - Oesophageal/Rectal.							
0212020	Temperature probe - Oesophageal/Rectal.	10	10	2	7	5	5	1
0212021	Temperature probe - Skin contact.	5				3		
0212022	Temperature probe - Skin contact.		10	1				
0212023	Temperature probe - Skin contact.	6	1					5
0212024	Temperature probe - Skin contact.							
0212025	Temperature probe - Skin contact.							
0212026	Temperature probe - Skin contact.		1					
0212027	Temperature probe - Skin contact.	2						
0212028	Temperature probe - Skin contact.	4						
0212029	Temperature probe - Skin contact.	2						
0212030	Temperature probe - Skin contact.	2		1				20
0212031	Temperature probe - Skin contact.	2	1	1	1			
0212032	Temperature probe - Skin contact.	2					4	2
0222000	Temperature probe - Series 400-AC							
0222001	Temperature probe - Series 400-AC							

Comments on Sales Information:

units selling in very low numbers

Countries Review

Country	2008	2009	2010	2011	2012	2013	2014
AU Austria	[X]						
CH Chile			[X]	[X]			
GR Greece	[X]						[X]
IN India	[X]						
IS Israel		[X]	[X]	[X]	[X]	[X]	
MA Malaysia		[X]					
OM Oman						[X]	
P Poland				[X]		[X]	[X]
PO Portugal		[X]					
T Turkey	[X]						
UK United Kingdom	[X]	[X]	[X]	[X]	[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
0212010	No Fault Return to Stock							
0212020	Cable open circuit			2				
0222000	Unchecked - Returned to Stock							

Comments on Returns:

Zero returns - mainly due to the very low sales figures

Comments on Risks with Returns and Potential Re-work:

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

Document ID	Description	Date Added/Updated
2952	400-AC Temperture Probes User Instructions	17/01/08

Comments on User Instructions:

no changes to 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
9169	No accessory labels	18/10/11
7092	Temperature Probes BPM Labels Tacking labels	20/05/10
6806	Temperature Probes BPM Labels 400AC	18/02/10
6805	Temperature Probes BPM Labels 400ACplug label II	18/02/10
6804	Temperature Probes BPM Labels 400AC plug label	18/02/10
6803	Temperature Probes BPM Labels 400AC Bag label	18/02/10
6802	Temperature Probes BPM Labels 400AC box label	18/02/10

Comments on Labels:

no changes to labels

Comments on Risks Labels:

n/a

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
13168	CE 540537 Certificate Customer Copy	22/11/13
13162	Temperature Probes BPM OES (OEM) Lables for OBLs (2)	19/11/13
13161	Temperature Probes BPM OES (OEM) Lables for OBLs (1)	19/11/13
13160	Temperature Probes BPM OES (OEM) Instructions for Use and Labels	19/11/13
13136	Generic CE File Attached to All Medicinal Substances None	31/10/13
13135	No Animal Tissues No Animal Substances	31/10/13
12819	Temperature Probes BPM Clinical Trials Reports Reviews and Post ...	30/07/13

Comments on Document Changes:

added OEM version of labels

Comments on Risks with Document Changes:

no risks identified

Internal Issues Review

Number of Issues reviewed: 4

Issue ID	Subject
46973	Customer order for 0212020
46972	Customer order for 0212020
48469	Greece - Temperature probes
48466	Greece - temperature probes

Comments on Issues:

sales queries

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 :

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