



VIA MED

Temperature Probes BPM

Reusable Temperature Probe

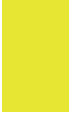
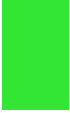
Class IIa

NBOG MD0101

Carried out by Derek Lamb
20 / 04 / 16



VIA MED

-  Stock References Review
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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

Supplier Review

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

Comments on Suppliers:

supplier review upto date

Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
0212009	Temperature probe - Oeso	7	1		2			
0212010	Temperature probe - Oeso	2	5		2			
0212011	Temperature probe - Oeso		2		2	9		
0212012	Temperature probe - Oeso							
0212013	Temperature probe - Oeso							
0212014	Temperature probe - Oeso		10					
0212015	Temperature probe - Oeso							
0212016	Temperature probe - Oeso							
0212017	Temperature probe - Oeso							
0212018	Temperature probe - Oeso					3		
0212019	Temperature probe - Oeso							
0212020	Temperature probe - Oeso	4	7	5	5	1	2	-1
0212021	Temperature probe - Skin			3			10	
0212022	Temperature probe - Skin	2					5	
0212023	Temperature probe - Skin					5	1	1
0212024	Temperature probe - Skin							
0212025	Temperature probe - Skin							
0212026	Temperature probe - Skin							
0212027	Temperature probe - Skin							
0212028	Temperature probe - Skin							
0212029	Temperature probe - Skin							
0212030	Temperature probe - Skin	1				17	10	5
0212031	Temperature probe - Skin	1	1				8	
0212032	Temperature probe - Skin				4	2	12	
0222000	Temperature probe - Seri							
0222001	Temperature probe - Seri							

Comments on Sales Information:

very limited number units selling,
will look at the product range end of 2016
Follow up Issue #70266

Countries Review

Country	2010	2011	2012	2013	2014	2015	2016
AU Austria							
CH Chile	[X]	[X]					
ES Estonia						[X]	
GR Greece					[X]		
IN India							
IS Israel	[X]	[X]	[X]	[X]			
MA Malaysia							
OM Oman				[X]			
P Poland		[X]		[X]	[X]	[X]	[X]
PO Portugal							
T Turkey							
UK United Kingdom	[X]	[X]	[X]		[X]	[X]	[X]

Comments on Sales to Countries:

ES Estonia
limited sales anywhere,

Comments on Risks with Sales to Countries:

no risks with countries

Returns Review

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
0212010	No Fault Return to Stock							
0212020	Cable open circuit	2						
0222000	Unchecked - Returned to Stock							

Comments on Returns:

no returns

Comments on Risks with Returns and Potential Re-work:

n/a no returns

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no design changes

Comments on Risks with Design Changes:

n/a no design changes

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 IFU

Comments on Risks User Instructions:

no risks identified with IFU

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
15362	Temperature Probes BPM Labels 0212032	05/08/15
15360	Temperature Probes BPM Labels 0212031	05/08/15
15358	Temperature Probes BPM Labels 0212030	05/08/15
15356	Temperature Probes BPM Labels 0212029	05/08/15
15353	Temperature Probes BPM Labels 0212028	05/08/15
15351	Temperature Probes BPM Labels 0212027	05/08/15
15349	Temperature Probes BPM Labels 0212026	05/08/15
15347	Temperature Probes BPM Labels 0212025	05/08/15
15345	Temperature Probes BPM Labels 0212024	05/08/15
15343	Temperature Probes BPM Labels 0212023	05/08/15
15341	Temperature Probes BPM Labels 0212022	05/08/15
15339	Temperature Probes BPM Labels 0212021	05/08/15
15337	Temperature Probes BPM Labels 0212020	05/08/15
15335	Temperature Probes BPM Labels 0212019	05/08/15
15333	Temperature Probes BPM Labels 0212018	05/08/15
15331	Temperature Probes BPM Labels 0212017	05/08/15
15329	Temperature Probes BPM Labels 0212016	05/08/15
15327	Temperature Probes BPM Labels 0212015	05/08/15
15325	Temperature Probes BPM Labels 0212014	05/08/15
15323	Temperature Probes BPM Labels 0212013	05/08/15
15321	Temperature Probes BPM Labels 0212012	05/08/15
15319	Temperature Probes BPM Labels 0212011	05/08/15
15317	Temperature Probes BPM Labels 0212010	05/08/15
15315	Label 0212009	05/08/15
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:

labels updated

Comments on Risks Labels:

no risks with labels

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
15418	PPE Equipment	11/08/15
15362	Temperature Probes BPM Labels 0212032	05/08/15
15360	Temperature Probes BPM Labels 0212031	05/08/15
15358	Temperature Probes BPM Labels 0212030	05/08/15
15356	Temperature Probes BPM Labels 0212029	05/08/15
15353	Temperature Probes BPM Labels 0212028	05/08/15
15351	Temperature Probes BPM Labels 0212027	05/08/15
15349	Temperature Probes BPM Labels 0212026	05/08/15
15347	Temperature Probes BPM Labels 0212025	05/08/15
15345	Temperature Probes BPM Labels 0212024	05/08/15
15343	Temperature Probes BPM Labels 0212023	05/08/15
15341	Temperature Probes BPM Labels 0212022	05/08/15
15339	Temperature Probes BPM Labels 0212021	05/08/15
15337	Temperature Probes BPM Labels 0212020	05/08/15
15335	Temperature Probes BPM Labels 0212019	05/08/15
15333	Temperature Probes BPM Labels 0212018	05/08/15
15331	Temperature Probes BPM Labels 0212017	05/08/15
15329	Temperature Probes BPM Labels 0212016	05/08/15
15327	Temperature Probes BPM Labels 0212015	05/08/15
15325	Temperature Probes BPM Labels 0212014	05/08/15
15323	Temperature Probes BPM Labels 0212013	05/08/15
15321	Temperature Probes BPM Labels 0212012	05/08/15
15319	Temperature Probes BPM Labels 0212011	05/08/15
15317	Temperature Probes BPM Labels 0212010	05/08/15
15315	Label 0212009	05/08/15
14886	Capnograph Expected Life of Products Various Products Blue poin...	27/03/15
14603	BPM DIN EN ISO Deutch BPM Bluepoint Medical ISO 13485	10/12/14
14602	BPM Annex II BPM Notified body certification Blue Point EC Certi...	10/12/14
14277	Temperature Probes BPM Clinical Trials Reports Reviews and Post ...	16/09/14

Comments on Document Changes:

labels updated

Comments on Risks with Document Changes:

no risks with documentation

Internal Issues Review

Number of Issues reviewed: 6

Issue ID	Subject
56033	Backorder 00000620 0212021 ORD72353
56733	Backorder 00000620 0212030 ORD72702
58000	Backorder 00000620 0212030 ORD73546
65423	Backorder 00007539 0212031 ORD77504
59193	Backorder 00007883 0212032 ORD74246
56864	Backorder 00012551 0212022 ORD72797

Comments on Issues:

very few issues,

Comments on Risks with Issues:

no risks with 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 :

Component of larger machines, no clinical data found just on the probes

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 :

Component of larger machines, no fda data found just on the probes