



VIA MED

Resuscitation Unit and TC400

Class I
Via Rule Rule 9
Assesment Route Annex II
NBOG MD 1100

Carried out by Derek Lamb
17 / 05 / 17



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
0120140	Adapter 15mm I.D. - 15mm I.D
0310001	Infant resuscitation cabinet.
0310002	Infant resuscitation cabinet.
0310003	Wall mounted cabinet including :
0310004	Cabinet - Type 2 no suction.
0310007	Infant resuscitation cabinet.
0310008	Infant resuscitation cabinet.
0310012	Infant resuscitation cabinet.
0310013	Infant resuscitation cabinet.
0310020	Storage bins size 3 blue.
0310025	Radiant warmer with double hinged arm
0310037	Rail mounted low suction controller
0310051	Infant resuscitation cabinet.
0310052	Infant resuscitation cabinet.
0310054	Infant resuscitation cabinet.
0310055	Infant resuscitation cabinet.
0310056	Infant resuscitation cabinet.
0310302	Radiant warmer with double hinged arm
0320010	Universal rail clamp with `V`
0320021	Resuscitation Bed 14 flat.``
0320023	Resuscitation Bed rotating.
0320039	Mattress octaganol - infant
0320043	Mattress large - infant resuscitation.
0320200	Mounting bracket - Medirail. For use
0330005	Resuscitation Cabinet Type 1
0330006	Door pad - for use with resus cabinet
0330007	Resuscitation Cabinet Door Hinge RHS.
0330008	Resuscitation Cabinet Door Hinge LHS.
0330009	Resuscitation Cabinet Door Catch
0330035	Suction clear tubing (1m)
0330105	Resuscitation Cabinet Type 2
0330106	Resuscitation Cabinet Type 3.
0332037	Resuscitation Cabinet Rail - Spacer 15mm
0332038	Resuscitation Cabinet Rail - Spacer 15mm
0332039	Resuscitation Cabinet Rail - Spacer 20mm
0332040	Resuscitation Cabinet Rail - Spacer 20mm
0332041	Resuscitation Cabinet Rail - Screw 35mm
0332042	Resuscitation Cabinet Rail - Screw 35mm
0332043	Resuscitation Cabinet Rail - Lock nut
0332044	Resuscitation Cabinet Rail - Lock nut
0332045	Resuscitation Cabinet Rail - Washer
0332046	Resuscitation Cabinet Rail - Washer

Stock Reference	Description
0332055	Resuscitation Cabinet Rail - 0.3m length
0332056	Resuscitation Cabinet Rail - 0.4m length
0332057	Resuscitation Cabinet Rail - 0.4m length
0332058	Resuscitation Cabinet Rail - 0.3m length
0332059	Resuscitation Cabinet Rail - 0.4m length
0332060	Resuscitation Cabinet MediRail ENDCAP
0332100	Resuscitation Cabinet Door Catch
0340010	Labour - Resuscitation Cabinet.
0340011	Training - Resuscitation Cabinet.
0350100	Packing box for resuscitation cabinet.
0380010	Annual service - Resuscitation cabinet.
0390000	B/W Resuscitation Cabinet Side 2
0390053	Label: Infant resuscitation cabinet.
0390100	Leaflet - Infant Resuscitation Cabinet.
0391055	Service sheet - Resuscitation Cabinet
3210071	Single use silicone round facemask
3833-007	Tapered connectors 10 per pack.
3833-132	1l VacSax canister with V mount.
9910-340	1l VacSax standard bore liners.Box of 25
9910-340S	1l VacSax standard bore liner - Single
9950050	Battery 1.5V AA 2700 mAh.

Comments on Stock references review:

parts number are correct

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0310025	Radiant warmer with doub	00007785	521A-60022OND	Nufer Medical AG	B
0310302	Radiant warmer with doub	00007785	521A-60022-3-OND	Nufer Medical AG	B
0320019	Resuscitation Bed 12 Fl	00009022	PP8720	Tanda Engineering Ltd	A
0320021	Resuscitation Bed 14 fl	00009022	PP8674	Tanda Engineering Ltd	A
0320023	Resuscitation Bed rotat	00009022	PP8762	Tanda Engineering Ltd	A
0332055	Resuscitation Cabinet Ra	00009022	PP8765	Tanda Engineering Ltd	A
0332056	Resuscitation Cabinet Ra	00009022	PP8766	Tanda Engineering Ltd	A
0332059	Resuscitation Cabinet Ra	00009022	PP8768	Tanda Engineering Ltd	A
0332056	Resuscitation Cabinet Ra	00009032	PP8766	R & L Enterprises Ltd	B
0332058	Resuscitation Cabinet Ra	00009032	PP8767	R & L Enterprises Ltd	B
0332059	Resuscitation Cabinet Ra	00009032	PP8768	R & L Enterprises Ltd	B
0332037	Resuscitation Cabinet Ra	00009045		Essentra Components	B
0320043	Mattress large - infant	00009054	0320043	Angel Healthcare Solutio	Needs Grading
0310020	Storage bins size 3 bl	00009061	2143013	Farnell	A
0330006	Door pad - for use with	00009061	1165061	Farnell	A
0332046	Resuscitation Cabinet Ra	00009061	1580684	Farnell	A
0360000	Hex wrench short arm 3	00009061	1552281	Farnell	A
9950051	Batteries 1.5V AA. Proce	00009061	MN1500 PACK 10	Farnell	A
0350040	Patient circuit (single	00009082	INT-6181	Intersurgical Ltd	B
0310037	Rail mounted low suction	00009150	4725-3M	Therapy Equipment Ltd	A
0320010	Universal rail clamp wit	00009150	2003	Therapy Equipment Ltd	A
0320030	1/2 litre suction jar an	00009150	4508	Therapy Equipment Ltd	A
0330035	Suction clear tubing (1m	00009150	4302	Therapy Equipment Ltd	A
0330055	Universal clamp - 44mm h	00009150	2002	Therapy Equipment Ltd	A
0390000	B/W Resuscitation Cabine	00009360	0390000	Print Centre	B
0390100	Leaflet - Infant Resusci	00009360		Print Centre	B
0390100	Leaflet - Infant Resusci	00009363		ACI Print Group Impress	B
0332056	Resuscitation Cabinet Ra	00009365	PP8766	WEC Machining	B
0332058	Resuscitation Cabinet Ra	00009365	PP8767	WEC Machining	B
0332059	Resuscitation Cabinet Ra	00009365	PP8768	WEC Machining	B
0310035	Low suction controller	00009450	S714916	Oxylitre	B
0310141	Injector low suction con	00009450	S801/L	Oxylitre	B
0330040	Suction hose assembly (3	00009450	S6666-3	Oxylitre	B
3210071	Single use silicone roun	00009602	M6200500D	Bunzl Healthcare	B
3210071	Single use silicone roun	00009721	M6200500D	Marshall Products Limite	B
0330238	Rectangular Bracket (G+R	00010160	0330238	KSJ Engineering Limited	B
0330005	Resuscitation Cabinet T	00010220	BA/10 TYPE 1	Bristol Maid	B
0330105	Resuscitation Cabinet Ty	00010220	SPRC11	Bristol Maid	B
0390053	Label: Infant resuscitat	00010665		Pendle Signs & Plastics	B
0332040	Resuscitation Cabinet Ra	00011727	1111630000VR	Plastic Parts Centre Ltd	B
3833-007	Tapered connectors 10 p	00011810	3833-007	Vacsax Ltd.	B
3833-132	1l VacSax canister with	00011810	3833-132	Vacsax Ltd.	B

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
9910-340	1l VacSax standard bore	00011810	9910-340	Vacsax Ltd.	B
0350100	Packing box for resuscit	00011818		Macfarlane Group	B
0120140	Adapter 15mm I.D. - 15m	00011844	PF 1515	Instrumentation Industri	A
0320039	Mattress octaganol - in	00012180	0320039	Park House Healthcare Lt	C
0320042	Mattress small - infant	00012180		Park House Healthcare Lt	C
0320043	Mattress large - infant	00012180	0320043	Park House Healthcare Lt	C
9950051	Batteries 1.5V AA. Proce	00012264	MN1500 PACK 10	H-Squared UK Electric Lt	B
0330009	Resuscitation Cabinet Do	00012266	B344-12	R P Hardware Ltd	B
0330105	Resuscitation Cabinet Ty	00012407	SPRC11	W Shuttleworth & Co	B

Comments on Suppliers:

Angel Health care chase by Purchasing and sent supplier review questionnaire

Sales Information

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
0120140	Adapter 15mm I.D. - 15m	28	38	120	57	149	90	
0310001	Infant resuscitation cabinet.							
0310002	Infant resuscitation cabinet.	41	15	38	10	7	12	7
0310003	Wall mounted cabinet including :							
0310004	Cabinet - Type 2 no suction.							
0310007	Infant resuscitation cabinet.							
0310008	Infant resuscitation cabinet.							
0310012	Infant resuscitation cabinet.							
0310013	Infant resuscitation cabinet.							
0310020	Storage bins size 3 bl							
0310025	Radiant warmer with doub							
0310037	Rail mounted low suction	3						
0310051	Infant resuscitation cabinet.							
0310052	Infant resuscitation cabinet.		1					
0310054	Infant resuscitation cabinet.							
0310055	Infant resuscitation cabinet.							
0310056	Infant resuscitation cabinet.							
0310302	Radiant warmer with doub				3			
0320010	Universal rail clamp wit		4					
0320021	Resuscitation Bed 14 fl	11	23	13	22	9	20	6
0320023	Resuscitation Bed rotat							
0320039	Mattress octaganol - in		1					
0320043	Mattress large - infant	-1	17	3	8	5	2	6
0320200	Mounting bracket - Medirail. For use	26	12	23	3	5		
0330005	Resuscitation Cabinet T							
0330006	Door pad - for use with							
0330007	Resuscitation Cabinet Door Hinge RHS.							
0330008	Resuscitation Cabinet Door Hinge LHS.							
0330009	Resuscitation Cabinet Do	3						
0330035	Suction clear tubing (1m			2	7	6		
0330105	Resuscitation Cabinet Ty		5	1	9	5	1	
0330106	Resuscitation Cabinet Type 3.							
0332037	Resuscitation Cabinet Ra							
0332038	Resuscitation Cabinet Rail - Spacer 15mm							
0332039	Resuscitation Cabinet Rail - Spacer 20mm					19		
0332040	Resuscitation Cabinet Ra							
0332041	Resuscitation Cabinet Rail - Screw 35mm					19		
0332042	Resuscitation Cabinet Rail - Screw 35mm							
0332043	Resuscitation Cabinet Rail - Lock nut					19		
0332044	Resuscitation Cabinet Rail - Lock nut							
0332045	Resuscitation Cabinet Rail - Washer					19		
0332046	Resuscitation Cabinet Ra							

Stock Reference	Description	2011	2012	2013	2014	2015	2016	2017
0332055	Resuscitation Cabinet Ra							
0332056	Resuscitation Cabinet Ra							
0332057	Resuscitation Cabinet Rail - 0.4m length		59	34	36		60	
0332058	Resuscitation Cabinet Ra		4	1	9	5		
0332059	Resuscitation Cabinet Ra		8	2	18	11		
0332060	Resuscitation Cabinet MediRail ENDCAP							
0332100	Resuscitation Cabinet Door Catch							
0340010	Labour - Resuscitation Cabinet.							
0340011	Training - Resuscitation Cabinet.							
0350100	Packing box for resuscit							
0380010	Annual service - Resuscitation cabinet.							
0390000	B/W Resuscitation Cabine							
0390053	Label: Infant resuscitat							
0390100	Leaflet - Infant Resusci			10	20			
0391055	Service sheet - Resuscitation Cabinet							
3210071	Single use silicone roun	1915	1514	874	648	734	839	260
3833-007	Tapered connectors 10 p		1			1		
3833-132	1l VacSax canister with		1		10			
9910-340	1l VacSax standard bore		4	3		2		
9910-340S	1l VacSax standard bore liner - Single							
9950050	Battery 1.5V AA 2700 mAh.							

Comments on Sales Information:

units still selling

Countries Review

Country	2011	2012	2013	2014	2015	2016	2017
B Belgium	[X]	[X]	[X]				
C China				[X]			
CAN Canada	[X]				[X]		
CZ Czech Republic				[X]			
DE Denmark			[X]				
F France			[X]				
FI Finland							
G Germany		[X]					
IRE Ireland			[X]				
IT Italy		[X]	[X]			[X]	
MA Malaysia							
NO Norway			[X]				
RU Russia	[X]	[X]	[X]				
SRI Sri Lanka					[X]		
SWI Switzerland			[X]				
T Turkey			[X]				
UAE U A E							
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

Sales Mainly in teh UK,

We get the odd request for export but mainly samples sent no real sales in teh last few years

Comments on Risks with Sales to Countries:

no risks

Returns and Q.A. Fails Review

Stock Reference	Fault	2011	2012	2013	2014	2015	2016	2017
0310002	Needs Evaluating							
0310025	Needs Evaluating							
0310025	Control Board Replaced			1				
0310025	No fault found			1				
0310025	Tested							
0320021	Needs Evaluating			1				
0320021	Unable to repair							
0320021	Unchecked - Returned to Stock			1				
0320043	Unchecked - Returned to Stock							

Comments on Returns:

Very few returns, and fewer faults.

Comments on Risks with Returns and Potential Re-work:

no risks with reworks

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

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
17738	Resuscitation Cabinet Instructions For Use (with Therapy Equipme...	24/10/16
17737	Resuscitation Cabinet Instructions For Use (with Oxylitre) v11.0	24/10/16
17736	Resuscitation Cabinet Operator Manual (without appedices)	24/10/16
14789	Instruction Manual - Air Oxygen Blenderl	19/02/15
14688	Ceratherm 300 Installation Instructions for modified casing part...	16/01/15
12878	0310140 - S8 series injector suction Operating Instructions	15/08/13
9241	Resuscitation Unit and TC400 Instructions for Use / Mobile Cerat...	18/10/11
8510	Resuscitation Unit and TC400 Instructions for Use User Manual O...	06/07/11
8509	Resuscitation Unit and TC400 Instructions for Use User Manual O...	06/07/11
8508	Resuscitation Unit and TC400 Instructions for Use User Manual T...	06/07/11
8507	Operators manual for Inspiration Blender Resuscitation Unit and ...	06/07/11
8179	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	24/03/11
8178	Resuscitation Unit Instructions for Use / Installation Ceratherm...	24/03/11
8176	Resuscitation Unit and TC400 Instructions for Use User Manual T...	24/03/11
8175	Resuscitation Unit and TC400 Instructions for Use User Manual A...	24/03/11
8170	Resuscitation Unit and TC400 Instructions for Use User Manual O...	24/03/11
8126	Resuscitation Unit and TC400 Instructions for Use TC400/W mkl	23/03/11
8124	Resuscitation Unit and TC400 Instructions for Use / User Manual	23/03/11
4128	Resuscitation Unit and TC400 Instructions for Use TC400 prevent...	09/07/08
4127	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4121	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4120	Resuscitation Unit and TC400 Instructions for Use / Therapy Equi...	09/07/08
4119	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4118	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4117	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4115	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4114	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4113	Resuscitation Unit and TC400 Instructions for Use / Ceratherm Ch...	09/07/08
4112	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
4101	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	09/07/08
3977	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	08/07/08
3976	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	08/07/08
3975	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	08/07/08
3974	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	08/07/08
3973	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	08/07/08
3972	Resuscitation Unit and TC400 Instructions for Use / User Manual ...	08/07/08
2573	Resuscitation Unit Instructions for Use / User Manual Apgar Time...	17/08/07
1511	User Manual Apgar Smiths NS 22G CE FILE Apgar Timer V1r Instruct...	09/05/07
1312	Resuscitation Unit Instructions for Use / User Manual Nufer Wall...	19/03/07
1308	Resuscitation Unit Instructions for Use / Operator Manual Cerat...	19/03/07
1303	Resuscitation Unit Instructions for Use / User Manual Oxylitre S...	19/03/07

Comments on User Instructions:

updated some component - other OEM products instruction manuals
CABinate IFU unchanged

Comments on Risks User Instructions:

no risks with IFU

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
15598	Resuscitation Unit and TC400 Labels (2)	07/09/15
8127	Resuscitation Unit and TC400 Labels (1)	23/03/11
4110	Resuscitation Unit and TC400 Labels Caution 2006	09/07/08
4109	Resuscitation Unit and TC400 Labels cabinet labels	09/07/08
4108	Resuscitation Unit and TC400 Labels 1989	09/07/08
3983	TC400 Rear Label original.pdf CE FILE Resuscitation Unit and TC4...	08/07/08
3981	Resuscitation Unit and TC400 Labels TC400 2001 (5).pdf	08/07/08
3980	Resuscitation Unit and TC400 Labels TC400 2001.pdf	08/07/08
3918	Resuscitation Unit Labels rotating bed	23/06/08
1319	Resuscitation Unit Labels Apgar Timer (2002)	19/03/07
1318	Resuscitation Unit Labels Thermacot 2	19/03/07
1317	Resuscitation Unit Labels Ceratherm 2006 Weee	19/03/07
1316	Resuscitation Unit Labels Thermacot	19/03/07
1315	Resuscitation Unit Labels Caution Label	19/03/07

Comments on Labels:

No changes to Labels

Comments on Risks Labels:

n/a

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
17738	Resuscitation Cabinet Instructions For Use (with Therapy Equipme...	24/10/16
17737	Resuscitation Cabinet Instructions For Use (with Oxyliure) v11.0	24/10/16
17736	Resuscitation Cabinet Operator Manual (without appedices)	24/10/16
17428	Viamed CE Certificate CE01389	07/09/16
17074	SERVICING OPTIONS and COSTS	23/06/16
16775	Resuscitation Unit and TC400 Clinical Trials Reports Reviews and...	18/04/16

Comments on Document Changes:

No document changes

Comments on Risks with Document Changes:

n/a

Internal Issues Review

Number of Issues reviewed: 97

Issue ID	Subject
79978	0310002 Price 0000 request Large Quantity
79977	0310002 Price 0000 request Large Quantity
79976	0310002 Price 0000 request Large Quantity
87852	0310302 mains cables
94435	0320021 stock level
70526	Backorder 00000200 0120140 ORD79968
78350	Backorder 00000262 0320021 ORD82157
94770	Backorder 00000790 0330105 ORD86308
85687	Backorder 00001002 0120140 ORD84018
77742	Backorder 00001310 0310002 ORD81979
85845	Backorder 00001480 0310002 ORD84004
92432	Backorder 00001910 0320021 ORD85735
75695	Backorder 00001995 0310200 ORD81487
73211	Backorder 00002040 3210071 ORD80894
73283	Backorder 00002040 3210071 ORD80910
73284	Backorder 00002040 3210071 ORD80911
74396	Backorder 00002040 3210071 ORD81194
74773	Backorder 00002040 3210071 ORD81268
74775	Backorder 00002040 3210071 ORD81272
76075	Backorder 00002040 3210071 ORD81631
78062	Backorder 00002040 3210071 ORD82088
78132	Backorder 00002040 3210071 ORD82089
84997	Backorder 00002040 3210071 ORD83814
87707	Backorder 00002040 3210071 ORD84537
88154	Backorder 00002040 3210071 ORD84664
93554	Backorder 00002040 3210071 ORD86044
93555	Backorder 00002040 3210071 ORD86045
85487	Backorder 00002370 0310002 ORD83938
73931	Backorder 00002609 0330105 ORD81072
73204	Backorder 00002950 0310002 ORD80875
93758	Backorder 00002950 0320043 ORD86091
90243	Backorder 00003720 0320021 ORD85137
75073	Backorder 00003785 0320021 ORD81341
79691	Backorder 00003785 0320021 ORD82405
72695	Backorder 00004260 0320021 ORD80711
75972	Backorder 00005363 0320021 ORD81583
71805	Backorder 00007359 0320200 ORD80371
90244	Backorder 00007476 0320200 ORD85139
94316	Backorder 00013016 0310002 ORD86183
68974	Cabinet parts for urgent order - North Cumbria Hospitals NHS Trust
94321	Cabinet spec for University of Hull - ORD86183
94320	Cabinet spec for University of Hull - ORD86183

Issue ID	Subject
92677	CCN149 Ceratherm 600-3 Serial No. 516-3-0514
55398	Ceratherm weights and dimensions
81374	Extended Descriptions
79286	Field Service visit 43
77234	Infant Grapevine Article: Ceratherm
77233	Infant Grapevine Article: Ceratherm
77232	Infant Grapevine Article: Ceratherm
77231	Infant Grapevine Article: Ceratherm
77230	Infant Grapevine Article: Ceratherm
77229	Infant Grapevine Article: Ceratherm
77228	Infant Grapevine Article: Ceratherm
77227	Infant Grapevine Article: Ceratherm
77226	Infant Grapevine Article: Ceratherm
77225	Infant Grapevine Article: Ceratherm
77443	New service visit to add and arrange - Diana Princess of Wales Hospital
77442	New service visit to add and arrange - Diana Princess of Wales Hospital
70488	POR10718 0320021 //
70486	POR10718 0320021 //
72075	POR10738 3210071 //
71155	POR10738 3210071 //
72121	POR10751 0310302 //
71710	POR10751 0310302 //
73483	POR10805 0310020 //
73428	POR10805 0310020 //
73694	POR10809 0320010 //
75148	POR10842 0320021 //
75137	POR10842 0320021 //
76001	POR10875 0320021 //
81509	POR10992 0330006 //
81202	POR10992 0330006 //
81590	POR11001 0320021 //
81584	POR11001 0320021 //
91348	POR11094 0330105 //
85611	POR11094 0330105 //
91366	POR11094 0330105 05/04/2017
86323	POR11096 0310302 //
86149	POR11096 0310302 //
89001	POR11135 3210071 //
88052	POR11135 3210071 //
87876	POR11135 3210071 //
90394	POR11183 3833-007 //
90395	POR11183 3833-132 //
94597	POR11266 0320021 //
94431	POR11266 0320021 //
94430	POR11267 0320043 //

Issue ID	Subject
60975	QA test procedure for 0310302
85511	Resus cabinets for Dumfries & Galloway
87595	Resuscitation cabinet spreadsheet
65593	Sales areas - Nufer Ceratherm 600-3 Radiant Warmers
77441	Service Visit 43
62125	Steri-Touch antibacterial coating
89791	Tom Thumb service letters
89790	Tom Thumb service letters
89789	Tom Thumb service letters
74253	Vacsax Bacticlear Instructions For Use

Comments on Issues:

CCN147 with regard an OEM product sold in conjunction with the cabinate,
No patient risk found during the risk assesment, this was backup by email by nufer whom also confirmed no patient risk.

Comments on Risks with Issues:

CCN147 with regard an OEM product sold in conjunction with the cabinate,
No patient risk found during the risk assesment, this was backup by email by nufer whom also confirmed no patient risk.

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 :

Its a storage Cabinate, no Clinical reports found or required

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 :

Its a storage Cabinate, no FDA reports found