



VIA MED

Tom Thumb

Hand held, gas powered resuscitation unit.

Class IIb
Via Rule Special Rule 9
Assesment Route Annex II
NBOG MD 1100

Carried out by Derek Lamb
10 / 10 / 16



VIA MED

-  Stock References Review
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Stock References Review

Stock Reference	Description
0310027	Tom Thumb Infant Resuscitator (Air).
0310029	Tom Thumb Infant Resuscitator (Air).
0310030	Tom Thumb Infant Resuscitator.
0310031	Tom Thumb Infant Resuscitator (Oxygen).
0310032	Tom Thumb Infant Resuscitator (Oxygen).
0310033	Tom Thumb Infant Resuscitator (Oxygen).
0310034	Tom Thumb Infant Resuscitator (Oxygen).
0310072	Tom Thumb Infant Resuscitator.
0310074	Tom Thumb Infant Resuscitator.
0310075	Tom Thumb Infant Resuscitator.
0310076	Tom Thumb Infant Resuscitator.
0310080	Tom Thumb Infant Resuscitator (RO).
0310082	Tom Thumb Infant Resuscitator (RO).
0310092	Tom Thumb Infant Resuscitator (TG).
0310093	Tom Thumb Infant Resuscitator.
0310094	Tom Thumb Infant Resuscitator.
0310096	Tom Thumb Oxygen Vent with Pole Mount
0310097	Tom Thumb Infant Resuscitator (TG).
0310098	Tom Thumb Oxygen Flow.
0310099	Tom Thumb Oxygen Vent.
0310250	Tom Thumb Conversion Kit.
0320102	Tom Thumb Rectangular Mounting Block.
0320103	Tom Thumb Rectangular Mounting Block.
0330185	Wing Nut Screw Black 25mm Thread
0330190	Universal clamp - 44mm horizontal
0330191	Clamp Spacer
0330193	Pressure gauge: 63mm dial -5 to +60 cmWG
0330200	TT460 MAIN Body Block
0330201	TT480/490 MAIN Body Block
0330202	TT495 MAIN Body Block
0330203	Pressure gauge for `Tom Thumb` Infant
0330204	Flowmeter (air) 0-15 Lpm
0330205	Flowmeter Meter Bolt
0330206	Blocking Bolt And Nut
0330207	Blanking Bolt
0330208	Inlet 10 mm
0330209	Outlet 15mm
0330210	Precision Valve
0330211	Adjustable Valve
0330212	Gauge Seal
0330213	O Ring Thick
0330214	O Ring Thin

Stock Reference	Description
0330215	Clamp Spacer
0330216	Screws For Clamp
0330217	Oxygen hose 1m. C/W indirect probe &
0330218	Oxygen Hose 3m. C/W indirect probe &
0330219	Right Angle For Hose
0330220	Fomblin OT20 Grease 100g tube
0330221	Lock Tight
0330222	Precision Valve Spring
0330223	Adjustable Valve Spring
0330224	Precision Valve Body
0330225	Precision/Adjustable Valve Seating
0330227	Precision/Adjustable Valve Seat
0330228	Precision Valve Adjustable Screw
0330229	Adjustable Valve Body
0330230	Adjustable Valve Screw
0330231	Adjustable Valve Internal Stop
0330232	Adjustable Valve Collar
0330233	Adjustable Valve Centre Screw
0330234	Adjustable Valve Side Screw
0330235	Inlet Restrictor
0330236	Replacement Gauge Face.
0330241	TT480/490 MAIN Body Block
0330242	Medirail Mounting Bracket
0330243	Adjustable Valve Side Screw. Bag 100
0330246	Blocking Bolt And Nut
0330247	Blanking Bolt
0330248	Inlet 10 mm
0330249	Outlet 15mm
0330250	Oxygen hose 1.5m. C/W DIN fitting:
0330251	Oxygen hose 3.0m. C/W DIN fitting:
0330263	Oxygen Hose 2m. C/W indirect probe &
0330268	Air Hose 3m. C/W indirect probe &
0330291	Inlet 10mm Thumbelina Inlet
0330292	Outlet 15mm Thumbelina
0330295	Outlet 10mm do not use
0330296	Blanking Bolt
0330297	Clamp Spacer - dove tailed.
0330300	Key Ring chain 1 inch ball
0330800	Label - pressure control for Tom Thumb
0340000	Labour - Tom Thumb infant resuscitator.
0340001	Training - Tom Thumb infant resuscitator
0340002	Training - Tom Thumb infant resuscitator
0350120	Packing box for Tom Thumb TT480.
0350121	Packing box for Tom Thumb TT490 Series.
0380000	Annual service - Tom Thumb

Stock Reference	Description
0380030	Tom Thumb Infant Resuscitator.
0390003	Tom Thumb Instruction Manual
0390004	Leaflet - Tom Thumb Infant Resuscitator.
0390005	Tom Thumb Training Manual
0390006	Tom Thumb Instruction Manual
0390007	Tom Thumb Instruction Manual
0390008	Tom Thumb Serial Number Label
0390009	`Tom Thumb` Label
0390011	Tom Thumb CE Label
0390015	Tom Thumb label
0390016	Address label for Tom Thumb gauge.
0390017	Gauge label - Tom Thumb
0390020	Tom Thumb Service Manual
0390021	Tom Thumb Service Manual TT460
0390022	Tom Thumb Service Manual TT480
0390023	Tom Thumb Service Manual TT490-15
0390024	Tom Thumb Service Manual TT496
0390060	Tom Thumb Instruction Manual - TT495

Comments on Stock references review:

part numbers upto date

Supplier Review

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0320221	Pole Clamp without slide	00007317	IHCPC1-SPECIAL	Inspiration Healthcare L	A
0320103	Tom Thumb Rectangular Mo	00009022	PP8694	Tanda Engineering Ltd	A
0330185	Wing Nut Screw Black 2	00009032	3335	R & L Enterprises Ltd	B
0330190	Universal clamp - 44mm h	00009032	A4916	R & L Enterprises Ltd	B
0330191	Clamp Spacer	00009032	A4917	R & L Enterprises Ltd	B
0330201	TT480/490 MAIN Body Bloc	00009032	0330201	R & L Enterprises Ltd	B
0330205	Flowmeter Meter Bolt	00009032	0330205	R & L Enterprises Ltd	B
0330206	Blocking Bolt And Nut	00009032	0330206	R & L Enterprises Ltd	B
0330208	Inlet 10 mm	00009032	0330208	R & L Enterprises Ltd	B
0330209	Outlet 15mm	00009032	0330209	R & L Enterprises Ltd	B
0330224	Precision Valve Body	00009032	0330224	R & L Enterprises Ltd	B
0330225	Precision/Adjustable Val	00009032	0330225	R & L Enterprises Ltd	B
0330227	Precision/Adjustable Val	00009032	0330227	R & L Enterprises Ltd	B
0330228	Precision Valve Adjustab	00009032	0330228	R & L Enterprises Ltd	B
0330229	Adjustable Valve Body	00009032	0330229	R & L Enterprises Ltd	B
0330230	Adjustable Valve Screw	00009032	0330230	R & L Enterprises Ltd	B
0330231	Adjustable Valve Interna	00009032	0330231	R & L Enterprises Ltd	B
0330232	Adjustable Valve Collar	00009032	0330232	R & L Enterprises Ltd	B
0330233	Adjustable Valve Centre	00009032	0330233	R & L Enterprises Ltd	B
0330234	Adjustable Valve Side Sc	00009032	0330234	R & L Enterprises Ltd	B
0330242	Medirail Mounting Bracke	00009032	822	R & L Enterprises Ltd	B
0330216	Screws For Clamp	00009061	483-9616	Farnell	A
0330234	Adjustable Valve Side Sc	00009073	0330234	Modern Screws	B
0330243	Adjustable Valve Side Sc	00009073	020865070206020	Modern Screws	B
0330193	Pressure gauge: 63mm dia	00009097	74656	GNW - Gauges North West	B
0330210	Precision Valve	00009117	9901-40	JNK Tooling	B
0330211	Adjustable Valve	00009117	9901-18	JNK Tooling	B
0330224	Precision Valve Body	00009117	0330224	JNK Tooling	B
0330227	Precision/Adjustable Val	00009117	0330227	JNK Tooling	B
0330228	Precision Valve Adjustab	00009117	0330228	JNK Tooling	B
0330230	Adjustable Valve Screw	00009117	0330230	JNK Tooling	B
0330234	Adjustable Valve Side Sc	00009117	0330234	JNK Tooling	B
0330235	Inlet Restrictor	00009117	0330235	JNK Tooling	B
0330207	Blanking Bolt	00009123	0330207	RS Components Ltd	B
0330213	O Ring Thick	00009123	129-050	RS Components Ltd	B
0330214	O Ring Thin	00009123	129-044	RS Components Ltd	B
0330216	Screws For Clamp	00009123	483-9616	RS Components Ltd	B
0330220	Fomblin OT20 Grease 100	00009123	666-4893	RS Components Ltd	B
0330221	Lock Tight	00009123	514-515	RS Components Ltd	B
0330296	Blanking Bolt	00009123	367-6098	RS Components Ltd	B
0320060	Flowmeter (Oxygen) 0-15	00009150	6501	Therapy Equipment Ltd	A
0330030	Dovetail (male)	00009150	4505	Therapy Equipment Ltd	A

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0330055	Universal clamp - 44mm h	00009150	2002	Therapy Equipment Ltd	A
0330204	Flowmeter (air) 0-15 Lpm	00009150	6502	Therapy Equipment Ltd	A
0330212	Gauge Seal	00009150	6650-05	Therapy Equipment Ltd	A
0330217	Oxygen hose 1m. C/W indi	00009150	ZZ HOSE 1M	Therapy Equipment Ltd	A
0330218	Oxygen Hose 3m. C/W indi	00009150	ZZ HOSE 3M	Therapy Equipment Ltd	A
0330250	Oxygen hose 1.5m. C/W DI	00009150		Therapy Equipment Ltd	A
0330251	Oxygen hose 3.0m. C/W DI	00009150		Therapy Equipment Ltd	A
0330263	Oxygen Hose 2m. C/W indi	00009150	ZZ HOSE 2M	Therapy Equipment Ltd	A
0330268	Air Hose 3m. C/W indirec	00009150	ZZ HOSE 3M	Therapy Equipment Ltd	A
0390006	Tom Thumb Instruction Ma	00009345		Duffield Printers	A
0390007	Tom Thumb Instruction Ma	00009345		Duffield Printers	A
0350120	Packing box for Tom Thum	00009353	RPT10B	Rajapack Ltd	B
0350121	Packing box for Tom Thum	00009353	RPT17B	Rajapack Ltd	B
0390004	Leaflet - Tom Thumb Infa	00009360		Print Centre	B
0390004	Leaflet - Tom Thumb Infa	00009363		ACI Print Group Impress	B
0390003	Tom Thumb Instruction Ma	00009366		Warwick Printing	B
0390006	Tom Thumb Instruction Ma	00009366		Warwick Printing	B
3210011	NeoPEEP neonatal single	00009602	M6800100BLUE	Bunzl Healthcare	C
3210071	Single use silicone roun	00009602	M6200500D	Bunzl Healthcare	C
3210011	NeoPEEP neonatal single	00009721	M6800100BLUE	Marshall Products Limite	B
3210071	Single use silicone roun	00009721	M6200500D	Marshall Products Limite	B
0330800	Label - pressure control	00009930		Renlim Labels	B
0330200	TT460 MAIN Body Block	00010160	0330200	KSJ Engineering Limited	B
0330201	TT480/490 MAIN Body Bloc	00010160	0330201	KSJ Engineering Limited	B
0330202	TT495 MAIN Body Block	00010160	0330202	KSJ Engineering Limited	B
0330205	Flowmeter Meter Bolt	00010160	0330205	KSJ Engineering Limited	B
0330206	Blocking Bolt And Nut	00010160	0330206	KSJ Engineering Limited	B
0330208	Inlet 10 mm	00010160	0330208	KSJ Engineering Limited	B
0330209	Outlet 15mm	00010160	0330209	KSJ Engineering Limited	B
0330215	Clamp Spacer	00010160	9901-22	KSJ Engineering Limited	B
0330241	TT480/490 MAIN Body Bloc	00010160	9901-01	KSJ Engineering Limited	B
0330246	Blocking Bolt And Nut	00010160	9901-06	KSJ Engineering Limited	B
0330248	Inlet 10 mm	00010160	4701-61	KSJ Engineering Limited	B
0330249	Outlet 15mm	00010160	9901-34	KSJ Engineering Limited	B
0330295	Outlet 10mm do not use	00010160	0330295	KSJ Engineering Limited	B
0330203	Pressure gauge for `Tom	00010395	611.10.063	Wika Instruments Ltd	B
0330236	Replacement Gauge Face.	00010395	1391682	Wika Instruments Ltd	B
0390015	Tom Thumb label	00010665	TT IR	Pendle Signs & Plastics	B
0390016	Address label for Tom Th	00010665	TT ADR	Pendle Signs & Plastics	B
0390017	Gauge label - Tom Thumb	00010665	TT VIA	Pendle Signs & Plastics	B
0330200	TT460 MAIN Body Block	00010725	0330200	MAJ Hi-Spec Ltd	B
0330201	TT480/490 MAIN Body Bloc	00010725	0330201	MAJ Hi-Spec Ltd	B
0330202	TT495 MAIN Body Block	00010725	0330202	MAJ Hi-Spec Ltd	B
0330205	Flowmeter Meter Bolt	00010725	0330205	MAJ Hi-Spec Ltd	B
0330206	Blocking Bolt And Nut	00010725	0330206	MAJ Hi-Spec Ltd	B

Stock Ref.	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0330207	Blanking Bolt	00010725	0330207	MAJ Hi-Spec Ltd	B
0330208	Inlet 10 mm	00010725	0330208	MAJ Hi-Spec Ltd	B
0330209	Outlet 15mm	00010725	0330209	MAJ Hi-Spec Ltd	B
0330219	Right Angle For Hose	00010770	2020	Chelmer Pneumatics Ltd	B
0120140	Adapter 15mm I.D. - 15m	00011844	PF 1515	Instrumentation Industri	B
0330222	Precision Valve Spring	00012028	C6409	Harlow Springs Limited	B
0330223	Adjustable Valve Spring	00012028	9968	Harlow Springs Limited	B
0330300	Key Ring chain 1 inch ba	00012395	BC6	Seton	B

Comments on Suppliers:

suppliers upto date,
sampling of a new supplier in progress rnl. but no product manufactured as yet.

Sales Information

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
0310027	Tom Thumb Infant Resuscitator (Air).							
0310029	Tom Thumb Infant Resuscitator (Air).							
0310030	Tom Thumb Infant Resuscitator.	90	146	259	94	129	67	46
0310031	Tom Thumb Infant Resuscitator (Oxygen).							
0310032	Tom Thumb Infant Resuscitator (Oxygen).	6			3			
0310033	Tom Thumb Infant Resuscitator (Oxygen).							
0310034	Tom Thumb Infant Resuscitator (Oxygen).		2		1	2	1	
0310072	Tom Thumb Infant Resuscitator.							
0310074	Tom Thumb Infant Resuscitator.							
0310075	Tom Thumb Infant Resuscitator.							
0310076	Tom Thumb Infant Resuscitator.							
0310080	Tom Thumb Infant Resuscitator (RO).			2				
0310082	Tom Thumb Infant Resuscitator (RO).							
0310092	Tom Thumb Infant Resuscitator (TG).							
0310093	Tom Thumb Infant Resuscitator.		4					
0310094	Tom Thumb Infant Resuscitator.		4		9		6	1
0310096	Tom Thumb Oxygen Vent with Pole Mount				1			
0310097	Tom Thumb Infant Resuscitator (TG).				5	7	18	16
0310098	Tom Thumb Oxygen Flow.							
0310099	Tom Thumb Oxygen Vent.				1	1		
0310250	Tom Thumb Conversion Kit.			6	6	28	3	33
0320102	Tom Thumb Rectangular Mounting Block.							
0320103	Tom Thumb Rectangular Mo							
0330185	Wing Nut Screw Black 2							
0330190	Universal clamp - 44mm h				2	100	50	
0330191	Clamp Spacer				1			
0330193	Pressure gauge: 63mm dia						19	19
0330200	TT460 MAIN Body Block							
0330201	TT480/490 MAIN Body Bloc		1					
0330202	TT495 MAIN Body Block				1			
0330203	Pressure gauge for `Tom	32	18	10	21	9		1
0330204	Flowmeter (air) 0-15 Lpm							
0330205	Flowmeter Meter Bolt							
0330206	Blocking Bolt And Nut		16	12	10			
0330207	Blanking Bolt							
0330208	Inlet 10 mm		46	12	10		5	
0330209	Outlet 15mm						15	1
0330210	Precision Valve	4	5		3	2	3	2
0330211	Adjustable Valve	4	2	2	3	3	5	1
0330212	Gauge Seal	78	51	40	28	28	69	34
0330213	O Ring Thick	18	98	8	34	193	90	49
0330214	O Ring Thin	163	504	48	227	137	534	344

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
0330215	Clamp Spacer							
0330216	Screws For Clamp	4						
0330217	Oxygen hose 1m. C/W indi	8			6	6	2	4
0330218	Oxygen Hose 3m. C/W indi	15	20	2	7	17	14	
0330219	Right Angle For Hose	1	2					
0330220	Fomblin OT20 Grease 100						1	
0330221	Lock Tight							
0330222	Precision Valve Spring			1				
0330223	Adjustable Valve Spring			2		1		
0330224	Precision Valve Body							
0330225	Precision/Adjustable Val							
0330227	Precision/Adjustable Val	1		2	1		2	3
0330228	Precision Valve Adjustab							
0330229	Adjustable Valve Body				1			1
0330230	Adjustable Valve Screw						4	
0330231	Adjustable Valve Interna							
0330232	Adjustable Valve Collar							
0330233	Adjustable Valve Centre							
0330234	Adjustable Valve Side Sc					3		
0330235	Inlet Restrictor	5					3	
0330236	Replacement Gauge Face.	22	12	5	13	14	24	10
0330241	TT480/490 MAIN Body Bloc							
0330242	Medirail Mounting Bracke							
0330243	Adjustable Valve Side Sc							
0330246	Blocking Bolt And Nut							
0330247	Blanking Bolt							
0330248	Inlet 10 mm							
0330249	Outlet 15mm							
0330250	Oxygen hose 1.5m. C/W DI							
0330251	Oxygen hose 3.0m. C/W DI							
0330263	Oxygen Hose 2m. C/W indi				3	12	2	
0330268	Air Hose 3m. C/W indirec							
0330291	Inlet 10mm Thumbelina Inlet							
0330292	Outlet 15mm Thumbelina							
0330295	Outlet 10mm do not use						8	
0330296	Blanking Bolt							
0330297	Clamp Spacer - dove tailed.	7						
0330300	Key Ring chain 1 inch ba							
0330800	Label - pressure control							
0340000	Labour - Tom Thumb infant resuscitator.							
0340001	Training - Tom Thumb infant resuscitator							
0340002	Training - Tom Thumb infant resuscitator							
0350120	Packing box for Tom Thum							
0350121	Packing box for Tom Thum							
0380000	Annual service - Tom Thumb							

Stock Reference	Description	2010	2011	2012	2013	2014	2015	2016
0380030	Tom Thumb Infant Resuscitator.							
0390003	Tom Thumb Instruction Ma							
0390004	Leaflet - Tom Thumb Infa		6		50		10	
0390005	Tom Thumb Training Manual							
0390006	Tom Thumb Instruction Ma	12	6			20		
0390007	Tom Thumb Instruction Ma	12	6					
0390008	Tom Thumb Serial Number Label							
0390009	`Tom Thumb` Label							
0390011	Tom Thumb CE Label							
0390015	Tom Thumb label							
0390016	Address label for Tom Th							
0390017	Gauge label - Tom Thumb							
0390020	Tom Thumb Service Manual							
0390021	Tom Thumb Service Manual TT460							
0390022	Tom Thumb Service Manual TT480							
0390023	Tom Thumb Service Manual TT490-15							
0390024	Tom Thumb Service Manual TT496							
0390060	Tom Thumb Instruction Manual - TT495							

Comments on Sales Information:

untis and parts still selling

Countries Review

Country	2010	2011	2012	2013	2014	2015	2016
B Belgium			[X]	[X]			
BRA Brazil							
C China					[X]		
CAN Canada							
CZ Czech Republic					[X]	[X]	
F France	[X]	[X]	[X]	[X]	[X]	[X]	[X]
HK Hong Kong		[X]					
IN India				[X]			
IT Italy	[X]						[X]
MA Malaysia							
NE Netherlands					[X]	[X]	
NG Nigera					[X]		
PA Pakistan						[X]	
RU Russia	[X]	[X]	[X]	[X]	[X]		[X]
SAU Saudi Arabia			[X]	[X]			
SRI Sri Lanka						[X]	
SWI Switzerland						[X]	
T Turkey			[X]	[X]			
UAE U A E							
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

Still selling units in multiple countries

Comments on Risks with Sales to Countries:

New country Pakistan, no risks identified

Returns Review

Stock Reference	Fault	2010	2011	2012	2013	2014	2015	2016
0310030	Adjusted factory set valves				3			
0310030	Calibrated Gauge						1	
0310030	Converted to TT480			1				
0310030	Customer Declined Quotation							2
0310030	Damaged Pressure Gauge	2				1	1	
0310030	n/a							
0310030	No Fault Found							2
0310030	No Fault Return to Stock							
0310030	Repaired clamp and serviced							1
0310030	Replace gauge and service					1	1	4
0310030	Replaced gauge face and service							1
0310030	Serviced							1
0310030	Serviced / adjusted factory set valves	1		3	11	11	10	11
0310030	Tested						1	1
0310031	Serviced							2
0310032	Adjusted factory set valves	1						
0310032	Calibrated Gauge							
0310032	Converted to TT480			1				
0310032	Damaged Pressure Gauge	1						
0310032	Serviced							
0310032	Serviced / adjusted factory set valves	2			1			
0310032	Tested				1			
0310033	Replace gauge and service						1	
0310033	Serviced							
0310034	Adjusted factory set valves							
0310034	Converted to TT480						1	
0310034	Damaged Pressure Gauge							
0310034	Serviced				1			
0310034	Serviced / adjusted factory set valves	2	1	1	2		5	
0310034	Unchecked - Returned to Stock							
0310080	Replace gauge and service					1		
0310094	Converted to TT480				9			
0310097	Serviced / adjusted factory set valves					1	1	1
0310098	Serviced / adjusted factory set valves					3	1	
0310099	Serviced / adjusted factory set valves					2		
0330217	Unchecked - Returned to Stock							
0390023	Serviced							

Comments on Returns:

Mainly the odd gauge broken - physically

good number of services carried out.

Comments on Risks with Returns and Potential Re-work:

no risks identified with the returns / reworks / servicing

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 changes

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
15572	Tom Thumb Instructions for Use / User Manual TT490-15	01/09/15
15571	Tom Thumb Instructions for Use User Manual TT480	01/09/15
15570	Tom Thumb Instructions for Use User Manual 0310027	01/09/15
15511	Tom Thumb Instructions for Use User Manual TT480 Instructions D...	24/08/15
15510	Tom Thumb Instructions for Use User Manual TT480 Instructions D...	24/08/15
15509	Tom Thumb Instructions for Use User Manual TT480 Instructions D...	24/08/15
13047	Tom Thumb Instructions for Use User Manual French	14/10/13
12211	Tom Thumb Instructions for Use User Manual TT495-15	30/11/12
11732	Tom Thumb Instructions for Use User Manual	23/03/12
8512	Tom Thumb Instructions for Use User Manual NeoPEEP	06/07/11
8506	Instructions For Use Tom Thumb TT495	06/07/11
5107	Instructions For Use Tom Thumb TT480	23/02/09

Comments on User Instructions:

no changes to IFU

Comments on Risks User Instructions:

n/a no changes to IFU

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
15638	Tom Thumb Labels Original labels	16/09/15
11748	Tom Thumb Labels 0390016 Address Sticker Round outside Gauge	27/03/12
11747	Tom Thumb Labels Caution Label 0390018 Top Block	27/03/12
11746	Tom Thumb Labels 0390017 Front of Gauge Sticker	27/03/12
11745	Tom Thumb Labels 0390015 Front Block Logo Sticker	27/03/12
11744	Tom Thumb Labels 0390010 Adjustable Value Sticker	27/03/12
11743	Tom Thumb Labels Part number to Label	27/03/12
11742	Tom Thumb Labels TT491 Serial	27/03/12
11741	Tom Thumb Labels TT490 Serial	27/03/12
11740	Tom Thumb Labels Serial TT480	27/03/12
5922	Tom Thumb Labels mediprema labels	14/05/09
2254	Tom Thumb Parts List Adj label 04	19/06/07
2204	Tom Thumb Labels Tomb Thumb Infant Resuscitator	19/06/07

Comments on Labels:

no changes to labels,

Comments on Risks Labels:

n/a no changes to ifu

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
17428	Viamed CE Certificate CE01389	07/09/16
17411	Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Cli...	06/09/16
17382	Tom Thumb Clinical Papers Clinical Papers Annex X 1.1d supporti...	03/09/16
17379	Tom Thumb Data Approach Database 2008 vma9001 service	02/09/16
17378	Tom Thumb Data Approach Database VMA9001 2007 service	02/09/16
17377	Tom Thumb Data Approach Database Queen elizabeth 1997 Invoice	02/09/16
17376	Tom Thumb Data Approach Database sunderland pre ce mark 1998	02/09/16
17375	Tom Thumb Data Approach Database proof of sale March 1999	02/09/16
17374	Tom Thumb Data Approach Database vma9001 2006.	02/09/16
17373	Tom Thumb Data Approach Database TT480 Tom Thumb Test Sheets VMA...	02/09/16
17372	Tom Thumb Data Approach Database Service record vma9001 2005	02/09/16
17371	Tom Thumb Data Approach Database 2016 vma9001 service	02/09/16
17370	Tom Thumb Data Approach Database 2010_2016 vma9001 services	02/09/16
17369	Tom Thumb Data Approach Database 2003 vma9001 service	02/09/16
17368	Tom Thumb Data Approach Database 1999 vma9001 service	02/09/16
17367	Tom Thumb Data Approach Database Sales Tom Thumbs 1998_1999	02/09/16
17366	Tom Thumb Data Approach Database 1994_TT490_Sales	02/09/16
17353	Tom Thumb Pre-Clinical Trials Data Tom Thumb summation annex X 1...	31/08/16
17336	Tom Thumb Clinical Papers	26/08/16
17334	Resuscitation Guide Neonatal Life support 2005 Tom Thumb Literat...	26/08/16
17333	Tom Thumb Literature reviews Royal Berkshire GL443 Neonatal Guid...	26/08/16
17332	Tom Thumb Literature reviews Nottingham Neonatal Service - Clini...	26/08/16
17331	Tom Thumb Literature reviews Royal Cornwall Newborn guide lines	26/08/16
17330	Tom Thumb Literature reviews Scottish Neonatal Resuscitation Cou...	26/08/16
17310	Tom Thumb Essential requirements	23/08/16
17307	Tom Thumb Literature reviews T-piece or self inflating bag for p...	23/08/16
17306	Tom Thumb Literature reviews Comparison of the T-piece resus...	23/08/16
16324	Tom Thumb OES (OEM) CE Certificate Wika ISO 9001:2008	17/02/16
16043	Tom Thumb Clinical Trials Reports Reviews and Post Market Survei...	26/11/15
15756	Tom Thumb Residual Risks to Benefits Residual risks 2015	30/09/15
15754	Tom Thumb Clinical Trials Reseach	30/09/15
15753	Tom Thumb Clinical Trials Research JSL	30/09/15
15751	Tom Thumb Risk analysis reports Risk assessment	30/09/15
15747	Tom Thumb Post Market Surveillance	29/09/15

Comments on Document Changes:

add proof / evidence documents to prove the device has been on the market since the early 90s. for the clinical evaluation report

Comments on Risks with Document Changes:

no risks identified in the documentation.

Internal Issues Review

Number of Issues reviewed: 116

Issue ID	Subject
9809	
7148	
63834	0121190 & 0121191 DEHP, Phthalates, PVC declaration
68502	0310032 service sheet
76372	0310097
76371	0310097
68678	0310097 Tom Thumb for Inspiration Healthcare
65919	0330262 1.5m, 0330265 5m
62951	Backorder 00000170 0310094 ORD76134
63209	Backorder 00000170 0380000 ORD76134
76985	Backorder 00000550 0380000 ORD81769
72356	Backorder 00001350 0330213 ORD80571
68683	Backorder 00001350 0340002 ORD79218
72068	Backorder 00001761 0330217 ORD80476
72443	Backorder 00001910 0330213 ORD80570
73324	Backorder 00001910 0330214 ORD80570
75695	Backorder 00001995 0310200 ORD81487
68684	Backorder 00002600 0380000 ORD79182
75658	Backorder 00002609 0330040 ORD81493
70447	Backorder 00003710 0310030 ORD79904
71782	Backorder 00003710 0380000 ORD80299
65424	Backorder 00003785 0310030 ORD77506
65343	Backorder 00003785 0330193 ORD77457
66709	Backorder 00003785 0330193 ORD78229
66660	Backorder 00003785 0330212 ORD78213
65734	Backorder 00003970 0330212 ORD77678
74162	Backorder 00004992 0380000 ORD81116
66891	Backorder 00006777 0310097 ORD78403
70202	Backorder 00006777 0310097 ORD79796
68803	Backorder 00007291 0310030 ORD79272
72421	Backorder 00007291 0310030 ORD80616
72422	Backorder 00007291 0310030 ORD80617
78593	Backorder 00007291 0310030 ORD82114
72423	Backorder 00007291 0330193 ORD80618
78661	Backorder 00007291 0330193 ORD82209
63860	Backorder 00012746 0310097 ORD76660
67306	Backorder 00012746 0310097 ORD78574
68710	Backorder 00012746 0310097 ORD79224
75491	Backorder 00012746 0310097 ORD81454
72208	Backorder 00012967 0330236 ORD80523
64028	Error on QA data pages
79286	Field Service visit 43

Issue ID	Subject
62914	Inspiration/Inditherm
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
72642	Poor chrome on 0330206, 0330208, 0330209
69660	POR10628 0330201 //
69545	POR10628 0330201 //
69661	POR10628 0330206 //
69546	POR10628 0330206 //
69662	POR10628 0330208 //
69547	POR10628 0330208 //
69663	POR10628 0330209 //
69548	POR10628 0330209 //
72126	POR10767 0330217 //
72125	POR10767 0330217 //
73782	POR10788 0330246 //
72839	POR10788 0330246 //
73783	POR10788 0330248 //
72840	POR10788 0330248 //
73784	POR10788 0330249 //
72841	POR10788 0330249 //
74490	POR10822 0330213 //
74420	POR10822 0330213 //
74491	POR10822 0330214 //
74421	POR10822 0330214 //
76133	POR10873 0330206 //
76134	POR10873 0330208 //
76135	POR10873 0330209 //
79259	POR10941 0330205 //
79238	POR10941 0330205 //
79260	POR10941 0330224 //
79239	POR10941 0330224 //
79262	POR10941 0330225 //
79261	POR10941 0330225 //
79241	POR10941 0330225 //
79240	POR10941 0330225 //
79263	POR10941 0330227 //
79242	POR10941 0330227 //
79264	POR10941 0330228 //
79243	POR10941 0330228 //
79265	POR10941 0330229 //
79244	POR10941 0330229 //
79266	POR10941 0330230 //
79245	POR10941 0330230 //
79267	POR10941 0330231 //
79246	POR10941 0330231 //

Issue ID	Subject
79268	POR10941 0330232 //
79247	POR10941 0330232 //
79269	POR10941 0330233 //
79248	POR10941 0330233 //
79270	POR10941 0330234 //
79249	POR10941 0330234 //
79255	POR10942 0330201 //
79234	POR10942 0330201 //
79256	POR10942 0330206 //
79235	POR10942 0330206 //
79257	POR10942 0330208 //
79236	POR10942 0330208 //
79258	POR10942 0330209 //
79237	POR10942 0330209 //
79254	POR10943 0330190 //
79233	POR10943 0330190 //
81076	POR10961 0330212 //
81067	POR10961 0330212 //
79899	POR10961 0330212 //
15140	Pricing of 0310030
69860	Quality issue 0330201
70434	Returned Items SOR699
77441	Service Visit 43
65304	Special price TT-480 Italy
68681	TOM THUMB 0330232 Adjustable valve collar
75534	Tom Thumb new producer
65305	TT-480 IFU translation required
76373	Web Site Question ID 941
67012	Website updates

Comments on Issues:

no non conformance or customer complaints found in the issues system
mainly just order fulfillment issues.

Comments on Risks with Issues:

no risk found 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 :

Clinical report and upto date search`s / evaluation carried out on 06-09-2016.
not performed a further 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 :

Nothing found online regarding FDA reports