

File ID16 Tom Thumb Essential Requirements 10 Nov 2017

General Requirement	Applied Standards	Notes	Files
ER Section Reference	Applied Standards	Section Notes	#DOCID *FolderLocation(s) Document Description

General Requirement	Applied Standards	Notes	Files
1		Some Files Refer To Competirion Which Validates The Theory Of The Tom THumb	#22375 CHART 35 Products On Market Risk Management Plan Post Market Surveillance #22482 *H 3 *E 8 Tom Thumb Post Market Surveillance #22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #17411 *H 3 *H 4 1 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up #2229 *H 3 Tom Thumb Clinical Trials (R) Clinical Trials 1997 #14011 *H 3 Tom Thumb Clinical Trials Reports #15733 *L 1 *H 3 *H 4 1 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Neonatal resuscitation – a practical approach. The experience of one UK tertiary neonatal unit #16043 *H 3 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Risk benefits #15731 *H 3 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_1 #15732 *H 3 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_2 #15734 *H 3 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance University of Kentucky / UK HealthCare Policy and Procedure RC04-04P #15754 *H 3 Tom Thumb Clinical Trials Reseach #15753 *H 3 Tom Thumb Clinical Trials Research JSL

General Requirement	Applied Standards	Notes	Files
			#7457 *Y 1 Tom Thumb Design Input Device History Air Oxygen calculations #7458 *Y 1 Tom Thumb Design Input Device History valve theory #22902 *Y 1 Tom Thumb Design Input Device History Background Notes for Tom Thumb Design SN #2360 *Y 1 Tom Thumb Design Input Device History Calculations of Flow #2361 *Y 1 *Y 2 Tom Thumb Design Input Device History Device History & Theory 2004 #2362 *Y 1 Tom Thumb Design Input Device History Device Theory 2005 #2363 *Y 1 Tom Thumb Design Input Device History Flow calculations #14007 *Y 1 *H 7 Tom Thumb Design Input Device History IMI positive pressure ventilator #2364 *Y 1 *M 3 Tom Thumb Design Input Device History Original Specification Relief pressures #2365 *Y 1 Tom Thumb Design Input Device History Restrictor calculations #22906 *Y 1 Tom Thumb Design Input Device History Tom Thumb Design #2183 *E 4 Tom Thumb EN ISO 14971:2001 Annex A #8489 *E 5 Tom Thumb EN ISO 14971:2001 Annex D #2970 *E 4 Tom Thumb EN1998 Risk Analysis #11669 *Y 3 Tom Thumb Product usability

General Requirement	Applied Standards	Notes	Files
			#15756 *E 11 Tom Thumb Residual Risks to Benefits Residual risks 2015 #15439 *H 3 Tom Thumb Risk / benefits assessment and Clinical Re evaluation #23843 *E 3 Tom Thumb Risk analysis reports Risk assessment #23831 *E 3 *E 11 Tom Thumb Risk analysis reports Risk analysis 2017 #2247 *M 3 Tom Thumb Specifications Technical Specification 1997 #13680 *M 3 *T 2 Tom Thumb Specifications Temperature Range #2996 *Y 15 Tom Thumb Validation 2005 validation #2458 *Y 15 Tom Thumb Validation Compliance #2997 *Y 15 Tom Thumb Validation design compliance #8106 VM3COP18 Post Market Surveillance #17824 VM3COP27.11 Performing a Technical File PMS and risk assessment #15453 VM3COP27.12 Clinical Evaluation Risk assessment Technical Files

General Requirement	Applied Standards	Notes	Files
1 i		Units Not Held By The User.Ergonomic Design Is Down The The Choice Of T Occluder Used By The User	#22375 CHART 35 Products On Market Risk Management Plan Post Market Surveillance #22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #22902 *Y 1 Tom Thumb Design Input Device History Background Notes for Tom Thumb Design SN #22906 *Y 1 Tom Thumb Design Input Device History Tom Thumb Design #11669 *Y 3 Tom Thumb Product usability #15756 *E 11 Tom Thumb Residual Risks to Benefits Residual risks 2015 #23843 *E 3 Tom Thumb Risk analysis reports Risk assessment

General Requirement	Applied Standards	Notes	Files
1 ii		For Use By Qualified And Trained Personnel Only All Incidents Resulting In Legal Action Have Placed The Onus On The Operator To The Satisfaction Of The UK RHMAny Other Papers Are Available Where The Tom Thumb Has Been Discussed In Depth	#22375 CHART 35 Products On Market Risk Management Plan Post Market Surveillance #17334 *L 1 *H 4 1 Resuscitation Guide Neonatal Life support 2005 Tom Thumb Literature reviews Resuscitation Council (UK) Newborn Life Support #22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #15733 *L 1 *H 3 *H 4 1 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Neonatal resuscitation – a practical approach. The experience of one UK tertiary neonatal unit #22902 *Y 1 Tom Thumb Design Input Device History Background Notes for Tom Thumb Design SN #22906 *Y 1 Tom Thumb Design Input Device History Tom Thumb Design #11732 *F 5 Tom Thumb Instructions for Use User Manual #15570 *F 5 Tom Thumb Instructions for Use User Manual 0310027 #13047 *F 5 Tom Thumb Instructions for Use User Manual French #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #15509 *F 5 Tom Thumb Instructions for Use User Manual TT480 Instructions Dutch Email #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15 #17306 *L 1 *H 4 1 Tom Thumb Literature reviews Comparison of the T-piece resuscitator with other neonatal manual ventilation devices: A qualitative review

General Requirement	Applied Standards	Notes	Files
			#22480 *L 1 Tom Thumb Literature reviews NewbornLifeSupportClinicalGuidelinesFor #17307 *L 1 *H 4 1 Tom Thumb Literature reviews T-piece or self inflating bag for positive pressure ventilation during delivery room resuscitation_ An RCT - Resuscitation #15756 *E 11 Tom Thumb Residual Risks to Benefits Residual risks 2015 #23843 *E 3 Tom Thumb Risk analysis reports Risk assessment

General Requirement	Applied Standards	Notes	Files
2 i		AS Opposed To The Bag System. The Tee Occluder (Tom THumb) Is State Of The Art	#22375 CHART 35 Products On Market Risk Management Plan Post Market Surveillance #7742 Generic CE File Attached to All Assignment of responsibility Risk Management #22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #22898 *F 4 Tom Thumb Description of Accessories Background Notes for Tom Thumb Accessories #22982 *F 4 Tom Thumb Description of Accessories NeoPeep File Location #22902 *Y 1 Tom Thumb Design Input Device History Background Notes for Tom Thumb Design SN #21716 *Y 1 Tom Thumb Design Input Device History BS EN 60601-1-6 2015 Non Compliance #21712 *Y 1 *Y 3 Tom Thumb Design Input Device History BS EN 62366-1 2015 non compliance #22906 *Y 1 Tom Thumb Design Input Device History Tom Thumb Design #22860 *J 1 Tom Thumb Location of responsibilities JK. Location of Responsibilities_Tom Thumb #15756 *E 11 Tom Thumb Residual Risks to Benefits Residual risks 2015 #23843 *E 3 Tom Thumb Risk analysis reports Risk assessment #23831 *E 3 *E 11 Tom Thumb Risk analysis reports Risk analysis 2017 #21556 *J 1 VM3COP02.02 Viamed Company Responsibility's organisation chart structure

General Requirement	Applied Standards	Notes	Files
2 ii	EN ISO 14971:2012		#22375 CHART 35 Products On Market Risk Management Plan Post Market Surveillance #22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #2183 *E 4 Tom Thumb EN ISO 14971:2001 Annex A #8489 *E 5 Tom Thumb EN ISO 14971:2001 Annex D #15756 *E 11 Tom Thumb Residual Risks to Benefits Residual risks 2015 #23843 *E 3 Tom Thumb Risk analysis reports Risk assessment
2 iii			#22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #2183 *E 4 Tom Thumb EN ISO 14971:2001 Annex A #8489 *E 5 Tom Thumb EN ISO 14971:2001 Annex D #2970 *E 4 Tom Thumb EN1998 Risk Analysis #15756 *E 11 Tom Thumb Residual Risks to Benefits Residual risks 2015 #23843 *E 3 Tom Thumb Risk analysis reports Risk assessment

General Requirement	Applied Standards	Notes	Files
2 iv		Warnings On Residual Risks Are Being Re-formed And Added Into The New Instruction Manual In Line With The Competition	#22375 CHART 35 Products On Market Risk Management Plan Post Market Surveillance #2183 *E 4 Tom Thumb EN ISO 14971:2001 Annex A #8489 *E 5 Tom Thumb EN ISO 14971:2001 Annex D #8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15 #15756 *E 11 Tom Thumb Residual Risks to Benefits Residual risks 2015 #23843 *E 3 Tom Thumb Risk analysis reports Risk assessment

General Requirement	Applied Standards	Notes	Files
3			#21694 *M 1 Product Control Tom Thumb #22482 *H 3 *E 8 Tom Thumb Post Market Surveillance #22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #5120 *H 3 Tom Thumb Clinical Information / Data #17411 *H 3 *H 4 1 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up #2229 *H 3 Tom Thumb Clinical Trials (R) Clinical Trials 1997 #14011 *H 3 Tom Thumb Clinical Trials Reports #15733 *L 1 *H 3 *H 4 1 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Neonatal resuscitation – a practical approach. The experience of one UK tertiary neonatal unit #16043 *H 3 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Risk benefits #15731 *H 3 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_1 #15732 *H 3 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_2 #15734 *H 3 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance University of Kentucky / UK HealthCare Policy and Procedure RC04-04P #15754 *H 3 Tom Thumb Clinical Trials Research

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			#15753 *H 3 Tom Thumb Clinical Trials Research JSL #2230 *H 3 Tom Thumb Clinical Trials RVI 1997 #2466 *H 3 Tom Thumb Clinical Trials Sunderland 1993 #7457 *Y 1 Tom Thumb Design Input Device History Air Oxygen calculations #7458 *Y 1 Tom Thumb Design Input Device History valve theory #22902 *Y 1 Tom Thumb Design Input Device History Background Notes for Tom Thumb Design SN #21716 *Y 1 Tom Thumb Design Input Device History BS EN 60601-1-6 2015 Non Compliance #21712 *Y 1 *Y 3 Tom Thumb Design Input Device History BS EN 62366-1 2015 non compliance #2360 *Y 1 Tom Thumb Design Input Device History Calculations of Flow #2361 *Y 1 *Y 2 Tom Thumb Design Input Device History Device History & Theory 2004 #2362 *Y 1 Tom Thumb Design Input Device History Device Theory 2005 #2363 *Y 1 Tom Thumb Design Input Device History Flow calculations #14007 *Y 1 *H 7 Tom Thumb Design Input Device History IMI positive pressure ventilator #2364 *Y 1 *M 3 Tom Thumb Design Input Device History Original Specification Relief pressures #2365 *Y 1 Tom Thumb Design Input Device History Restrictor calculations

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			#22906 *Y 1 Tom Thumb Design Input Device History Tom Thumb Design #15461 *M 1 Tom Thumb Packaging Trials and validation #7724 *M 1 Tom Thumb Packaging Trials and validation Packagine TT480 #2245 *M 1 Tom Thumb Packaging Trials and validation Packaging Photographs 2004 #2244 *M 1 Tom Thumb Packaging Trials and validation Packaging Trial 2004 #7726 *M 1 Tom Thumb Packaging Trials and validation TT495 #15439 *H 3 Tom Thumb Risk / benefits assessment and Clinical Re evaluation #2247 *M 3 Tom Thumb Specifications Technical Specification 1997 #13680 *M 3 *T 2 Tom Thumb Specifications Temperature Range #23511 *M 3 *Y 10 Tom Thumb Specifications Wlka quote gauge cmH2o #2471 *Y 18 Tom Thumb Test Reports #9476 *Y 18 Tom Thumb Test Reports Dual Tom Thumb Flowrates #3000 *Y 18 Tom Thumb Test Reports Flow checks Test Results #2460 *Y 18 Tom Thumb Test Reports Flush rayes 2000 #2999 *Y 18

General Requirement	Applied Standards	Notes	Files
			Tom Thumb Test Reports TT Peep Results #2462 *Y 18 Tom Thumb Test Reports Wika calibration #2996 *Y 15 Tom Thumb Validation 2005 validation #2458 *Y 15 Tom Thumb Validation Compliance #2997 *Y 15 Tom Thumb Validation design compliance #2459 *Y 15 Tom Thumb Validation Project Validation #8106 VM3COP18 Post Market Surveillance #17824 VM3COP27.11 Performing a Technical File PMS and risk assessment #15453 VM3COP27.12 Clinical Evaluation Risk assessment Technical Files #15375 *G 3 *N 4 *J 5 VM3COP50.01 Tom Thumb TT490 (0310031 / 0310033) #15373 *G 3 *N 4 *J 5 VM3COP50.02 Tom Thumb production procedures TT480 (0310030) #15377 *G 3 *N 4 *J 5 VM3COP50.03.2 Tom Thumb TT490_15_Restricted #15379 *G 3 *N 4 *J 5 VM3COP50.04 Tom Thumb TT495 #8660 *G 3 *N 4 *J 5 VM3COP50.05 Tom Thumb Adjustable Valve #8661 *G 3 *N 4 *J 5 VM3COP50.06 Tom Thumb Precision Valve

General Requirement	Applied Standards	Notes	Files
			#11903 *J 5 VM3COP50.08 0310250 Convert TT490 to TT480 #12199 *J 5 VM3COP50.09 Tom Thumb TT490 - TT480 Conversion Procedure #12201 *J 5 VM3COP50.091 Tom Thumb TT490 - TT480 Conversion Procedure Customer Reply Notification #12301 *J 5 VM3COP50.10 Tom Thumb TT480 (0310094) #15367 *J 5 VM3COP50.12 Quality Control / Service Checks Tom Thumb #15365 *N 4 *J 5 VM3COP50.13 Quality Control Tom Thumb #23431 *N 4 *J 5 VM3COP50.14 Calibration / Test Sheet Blank Tom Thumbs #15385 *M 2 *N 4 *J 5 VM3COP50.15 Packaging Procedures Tom Thumbs #15387 *J 5 VM3COP50.16 TT480 Top Gauge 0310097 #15390 *J 5 VM3COP50.17 Tom Thumb 30CM limited QA Sheet

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4			#22375 CHART 35 Products On Market Risk Management Plan Post Market Surveillance #22482 *H 3 *E 8 Tom Thumb Post Market Surveillance #22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #5120 *H 3 Tom Thumb Clinical Information / Data #17411 *H 3 *H 4 1 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up #2229 *H 3 Tom Thumb Clinical Trials (R) Clinical Trials 1997 #14011 *H 3 Tom Thumb Clinical Trials Reports #15733 *L 1 *H 3 *H 4 1 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Neonatal resuscitation – a practical approach. The experience of one UK tertiary neonatal unit #15734 *H 3 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance University of Kentucky / UK HealthCare Policy and Procedure RC04-04P #2230 *H 3 Tom Thumb Clinical Trials RVI 1997 #2466 *H 3 Tom Thumb Clinical Trials Sunderland 1993 #2183 *E 4 Tom Thumb EN ISO 14971:2001 Annex A #8489 *E 5 Tom Thumb EN ISO 14971:2001 Annex D #2970 *E 4 Tom Thumb EN1998 Risk Analysis

General Requirement	Applied Standards	Notes	Files
			#11775 *G 7 Tom Thumb Expected Life of Products #20966 *G 7 Tom Thumb Expected Life of Products Proof1 #20968 *G 7 Tom Thumb Expected Life of Products Proof2 #22519 *G 7 Tom Thumb Expected Life of Products Tom Thumb life Rationale (Internal document) #2215 *G 4 Tom Thumb Product Life #22910 *G 4 Tom Thumb Product Life Background Notes for Tom Thumb Life expectancy #21995 *G 4 *G 7 *H 2 Tom Thumb Product Life User feedback old tom thumbs #15439 *H 3 Tom Thumb Risk / benefits assessment and Clinical Re evaluation #23843 *E 3 Tom Thumb Risk analysis reports Risk assessment #23831 *E 3 *E 11 Tom Thumb Risk analysis reports Risk analysis 2017

General Requirement	Applied Standards	Notes	Files
5			#21694 *M 1 Product Control Tom Thumb #22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #2991 *T 2 Tom Thumb Material Safety Data Sheet 2004 MH052_MSDS_20050405 #15461 *M 1 Tom Thumb Packaging Trials and validation #7724 *M 1 Tom Thumb Packaging Trials and validation Packagine TT480 #2245 *M 1 Tom Thumb Packaging Trials and validation Packaging Photographs 2004 #2244 *M 1 Tom Thumb Packaging Trials and validation Packaging Trial 2004 #7726 *M 1 Tom Thumb Packaging Trials and validation TT495 #11763 *U 1 Tom Thumb Purchase specifications 0330203 Pressure Gauge #22494 *U 1 Tom Thumb Purchase specifications Flowmeter #22492 *U 1 Tom Thumb Purchase specifications Fomblin RT15 #2347 *U 1 Tom Thumb Purchase specifications Fromlim #19538 *U 1 *G 5 Tom Thumb Purchase specifications GNW Instrumentation - Tom Thumb pressure gauge Tom Thumb Product Changes gauge #2356 *U 1 Tom Thumb Purchase specifications R S #2355 *U 1

General Requirement	Applied Standards	Notes	Files
			Tom Thumb Purchase specifications Wika #22490 *U 1 Tom Thumb Purchase specifications Wika 6111.10 gauge #13680 *M 3 *T 2 Tom Thumb Specifications Temperature Range
6			#22375 CHART 35 Products On Market Risk Management Plan Post Market Surveillance #22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #15756 *E 11 Tom Thumb Residual Risks to Benefits Residual risks 2015 #23843 *E 3 Tom Thumb Risk analysis reports Risk assessment

General Requirement	Applied Standards	Notes	Files
6 ii			#22482 *H 3 *E 8 Tom Thumb Post Market Surveillance #17411 *H 3 *H 4 1 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up #15733 *L 1 *H 3 *H 4 1 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance Neonatal resuscitation – a practical approach. The experience of one UK tertiary neonatal unit #15731 *H 3 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_1 #15732 *H 3 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance T-piece_resuscitator_2 #15734 *H 3 Tom Thumb Clinical Trials Reports Reviews and Post Market Surveillance University of Kentucky / UK HealthCare Policy and Procedure RC04-04P #15754 *H 3 Tom Thumb Clinical Trials Research #15753 *H 3 Tom Thumb Clinical Trials Research JSL #2466 *H 3 Tom Thumb Clinical Trials Sunderland 1993 #11656 *L 1 *Y 15 *H 4 *H 4 1 Tom Thumb Literature reviews Use of self-inflating bags #15454 *L 1 Tom Thumb Literature reviews Aired leaflet PIP & PEEP against bag

General Requirement	Applied Standards	Notes	Files
7.1 i			#2534 *T 1 MH052 TDS UK Permabond #2223 *H 1 *Y 16 Tom Thumb Analysis of complaints Complaints Internal 1994 #2474 *Z 6 Tom Thumb Bio-compatibility #7896 *Y 16 Tom Thumb Design Reviews QC24 #4298 *Y 16 Tom Thumb Design Reviews QC24 Thumbelina Mediprema FeedBack 2008 June #2998 *Y 16 Tom Thumb Design Reviews QC24 Drager Design review #2452 *Y 16 Tom Thumb Design Reviews QC24 Product Review 01 #2453 *Y 16 Tom Thumb Design Reviews QC24 Product Review 02 #2454 *Y 16 Tom Thumb Design Reviews QC24 Product Review Restrictor 02 #2455 *Y 16 Tom Thumb Design Reviews QC24 Product Review_03 #2456 *Y 16 Tom Thumb Design Reviews QC24 TT Restrictor #2991 *T 2 Tom Thumb Material Safety Data Sheet 2004 MH052_MSDS_20050405 #3003 *T 1 Tom Thumb Specifications of Materials 1997 Buckingham fastners 001 #3004 *T 1 Tom Thumb Specifications of Materials 1997 G R Hydroparts 001 #3005 *T 1 Tom Thumb Specifications of Materials 1997 Harlow 001

General Requirement	Applied Standards	Notes	Files
			#3007 *T 1 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001 #3008 *T 1 Tom Thumb Specifications of Materials 1997 Wika #3009 *T 1 Tom Thumb Specifications of Materials 1997 Wika 4 001 #3010 *T 1 Tom Thumb Specifications of Materials 1998 GSM 4 001 #2337 *T 1 Tom Thumb Specifications of Materials Dial a flow 1994 #2338 *T 1 Tom Thumb Specifications of Materials Fomblin grease #22488 *T 1 Tom Thumb Specifications of Materials Nitrile O rings #2340 *T 1 Tom Thumb Specifications of Materials O rings 1997 #2341 *T 1 Tom Thumb Specifications of Materials T E Copper washers #2342 *T 1 Tom Thumb Specifications of Materials TE Flowmeters #2343 *T 1 Tom Thumb Specifications of Materials TE guage 1997 9901-15 #7887 *T 1 Tom Thumb Specifications of Materials Therapy Equipment Flow meter #7884 *T 1 *Z 6 Tom Thumb Specifications of Materials TT component specifications all #3477 *T 1 *M 4 Tom Thumb Specifications of Materials TT0100-25 Blocking Bolt & Nut 0330206 #13680 *M 3 *T 2

General Requirement	Applied Standards	Notes	Files
			Tom Thumb Specifications Temperature Range

General Requirement	Applied Standards	Notes	Files
7.1 ii			#2534 *T 1 MH052 TDS UK Permabond #2223 *H 1 *Y 16 Tom Thumb Analysis of complaints Complaints Internal 1994 #7896 *Y 16 Tom Thumb Design Reviews QC24 #4298 *Y 16 Tom Thumb Design Reviews QC24 Thumbelina Mediprema FeedBack 2008 June #2998 *Y 16 Tom Thumb Design Reviews QC24 Drager Design review #2452 *Y 16 Tom Thumb Design Reviews QC24 Product Review 01 #2453 *Y 16 Tom Thumb Design Reviews QC24 Product Review 02 #2454 *Y 16 Tom Thumb Design Reviews QC24 Product Review Restrictor 02 #2455 *Y 16 Tom Thumb Design Reviews QC24 Product Review_03 #2456 *Y 16 Tom Thumb Design Reviews QC24 TT Restrictor #2991 *T 2 Tom Thumb Material Safety Data Sheet 2004 MH052_MSDS_20050405 #3003 *T 1 Tom Thumb Specifications of Materials 1997 Buckingham fastners 001 #3004 *T 1 Tom Thumb Specifications of Materials 1997 G R Hydroparts 001 #3005 *T 1 Tom Thumb Specifications of Materials 1997 Harlow 001 #3007 *T 1 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001

General Requirement	Applied Standards	Notes	Files
			#3008 *T 1 Tom Thumb Specifications of Materials 1997 Wika #3009 *T 1 Tom Thumb Specifications of Materials 1997 Wika 4 001 #3010 *T 1 Tom Thumb Specifications of Materials 1998 GSM 4 001 #2337 *T 1 Tom Thumb Specifications of Materials Dial a flow 1994 #2338 *T 1 Tom Thumb Specifications of Materials Fomblin grease #22488 *T 1 Tom Thumb Specifications of Materials Nitrile O rings #2340 *T 1 Tom Thumb Specifications of Materials O rings 1997 #2341 *T 1 Tom Thumb Specifications of Materials T E Copper washers #2342 *T 1 Tom Thumb Specifications of Materials TE Flowmeters #2343 *T 1 Tom Thumb Specifications of Materials TE guage 1997 9901-15 #7887 *T 1 Tom Thumb Specifications of Materials Therapy Equipment Flow meter #7884 *T 1 *Z 6 Tom Thumb Specifications of Materials TT component specifications all #3477 *T 1 *M 4 Tom Thumb Specifications of Materials TT0100-25 Blocking Bolt & Nut 0330206

General Requirement	Applied Standards	Notes	Files
7.1 iii			#22375 CHART 35 Products On Market Risk Management Plan Post Market Surveillance #22482 *H 3 *E 8 Tom Thumb Post Market Surveillance #22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #2474 *Z 6 Tom Thumb Bio-compatibility #5120 *H 3 Tom Thumb Clinical Information / Data #17411 *H 3 *H 4 1 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up #2229 *H 3 Tom Thumb Clinical Trials (R) Clinical Trials 1997 #14011 *H 3 Tom Thumb Clinical Trials Reports #2230 *H 3 Tom Thumb Clinical Trials RVI 1997 #2466 *H 3 Tom Thumb Clinical Trials Sunderland 1993 #2183 *E 4 Tom Thumb EN ISO 14971:2001 Annex A #8489 *E 5 Tom Thumb EN ISO 14971:2001 Annex D #2970 *E 4 Tom Thumb EN1998 Risk Analysis #15461 *M 1 Tom Thumb Packaging Trials and validation #7724 *M 1

General Requirement	Applied Standards	Notes	Files
			Tom Thumb Packaging Trials and validation Packagine TT480 #2245 *M 1 Tom Thumb Packaging Trials and validation Packaging Photographs 2004 #2244 *M 1 Tom Thumb Packaging Trials and validation Packaging Trial 2004 #7726 *M 1 Tom Thumb Packaging Trials and validation TT495 #15439 *H 3 Tom Thumb Risk / benefits assessment and Clinical Re evaluation #23843 *E 3 Tom Thumb Risk analysis reports Risk assessment #23831 *E 3 *E 11 Tom Thumb Risk analysis reports Risk analysis 2017 #7884 *T 1 *Z 6 Tom Thumb Specifications of Materials TT component specifications all
7.1 iv			

General Requirement	Applied Standards	Notes	Files
7.2			#22375 CHART 35 Products On Market Risk Management Plan Post Market Surveillance #21694 *M 1 Product Control Tom Thumb #22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #17411 *H 3 *H 4 1 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up #2183 *E 4 Tom Thumb EN ISO 14971:2001 Annex A #8489 *E 5 Tom Thumb EN ISO 14971:2001 Annex D #2970 *E 4 Tom Thumb EN1998 Risk Analysis #9474 *E 6 Tom Thumb Leakage and Liquid damage #15461 *M 1 Tom Thumb Packaging Trials and validation #7724 *M 1 Tom Thumb Packaging Trials and validation Packagine TT480 #2245 *M 1 Tom Thumb Packaging Trials and validation Packaging Photographs 2004 #2244 *M 1 Tom Thumb Packaging Trials and validation Packaging Trial 2004 #7726 *M 1 Tom Thumb Packaging Trials and validation TT495 #23843 *E 3 Tom Thumb Risk analysis reports Risk assessment #23831 *E 3 *E 11

General Requirement	Applied Standards	Notes	Files
			Tom Thumb Risk analysis reports Risk analysis 2017

General Requirement	Applied Standards	Notes	Files
7.3			#2534 *T 1 MH052 TDS UK Permabond #22482 *H 3 *E 8 Tom Thumb Post Market Surveillance #5120 *H 3 Tom Thumb Clinical Information / Data #17411 *H 3 *H 4 1 Tom Thumb Clinical Papers Annex X 1.1d Tom Thumb Post Market Clinical Evaluation Follow-up #2229 *H 3 Tom Thumb Clinical Trials (R) Clinical Trials 1997 #14011 *H 3 Tom Thumb Clinical Trials Reports #2230 *H 3 Tom Thumb Clinical Trials RVI 1997 #2466 *H 3 Tom Thumb Clinical Trials Sunderland 1993 #2991 *T 2 Tom Thumb Material Safety Data Sheet 2004 MH052_MSDS_20050405 #15439 *H 3 Tom Thumb Risk / benefits assessment and Clinical Re evaluation #3003 *T 1 Tom Thumb Specifications of Materials 1997 Buckingham fastners 001 #3004 *T 1 Tom Thumb Specifications of Materials 1997 G R Hydroparts 001 #3005 *T 1 Tom Thumb Specifications of Materials 1997 Harlow 001 #3007 *T 1 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001 #3008 *T 1

General Requirement	Applied Standards	Notes	Files
			Tom Thumb Specifications of Materials 1997 Wika #3009 *T 1 Tom Thumb Specifications of Materials 1997 Wika 4 001 #3010 *T 1 Tom Thumb Specifications of Materials 1998 GSM 4 001 #2337 *T 1 Tom Thumb Specifications of Materials Dial a flow 1994 #2338 *T 1 Tom Thumb Specifications of Materials Fomblin grease #2340 *T 1 Tom Thumb Specifications of Materials O rings 1997 #2341 *T 1 Tom Thumb Specifications of Materials T E Copper washers #2342 *T 1 Tom Thumb Specifications of Materials TE Flowmeters #2343 *T 1 Tom Thumb Specifications of Materials TE guage 1997 9901-15 #7887 *T 1 Tom Thumb Specifications of Materials Therapy Equipment Flow meter #7884 *T 1 *Z 6 Tom Thumb Specifications of Materials TT component specifications all #3477 *T 1 *M 4 Tom Thumb Specifications of Materials TT0100-25 Blocking Bolt & Nut 0330206 #2471 *Y 18 Tom Thumb Test Reports #9476 *Y 18 Tom Thumb Test Reports Dual Tom Thumb Flowrates #3000 *Y 18 Tom Thumb Test Reports Flow checks Test Results

General Requirement	Applied Standards	Notes	Files
			#2460 *Y 18 Tom Thumb Test Reports Flush rayes 2000 #2999 *Y 18 Tom Thumb Test Reports TT Peep Results #2461 *Y 18 Tom Thumb Test Reports Wika cal p02 #2462 *Y 18 Tom Thumb Test Reports Wika calibration
7.4			#9455 *Z 11 Carcinogenic Substances #9456 *Z 12 Generic CE File Attached to All Ionising Radiation None #8315 *Z 13 Human Blood & derivatives Statement of non use #13135 *Z 10 No Animal Tissues No Animal Substances

General Requirement	Applied Standards	Notes	Files
7.5			#9455 *Z 11 Carcinogenic Substances #9456 *Z 12 Generic CE File Attached to All Ionising Radiation None #8315 *Z 13 Human Blood & derivatives Statement of non use #13136 *Z 8 Medicinal Substances None #13135 *Z 10 No Animal Tissues No Animal Substances #22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #9474 *E 6 Tom Thumb Leakage and Liquid damage
7.6			#22375 CHART 35 Products On Market Risk Management Plan Post Market Surveillance #22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #2183 *E 4 Tom Thumb EN ISO 14971:2001 Annex A #8489 *E 5 Tom Thumb EN ISO 14971:2001 Annex D #2970 *E 4 Tom Thumb EN1998 Risk Analysis #23843 *E 3 Tom Thumb Risk analysis reports Risk assessment #23831 *E 3 *E 11 Tom Thumb Risk analysis reports Risk analysis 2017

General Requirement	Applied Standards	Notes	Files
8.1			#8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15
8.2			#13135 *Z 10 No Animal Tissues No Animal Substances
8.3			#22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #2253 *O 1 Tom Thumb Sterilisation #22531 *O 1 Tom Thumb Sterilisation Tomb Thumb Sterility
8.4			#22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #2253 *O 1 Tom Thumb Sterilisation #22531 *O 1 Tom Thumb Sterilisation Tomb Thumb Sterility

General Requirement	Applied Standards	Notes	Files
8.5			#22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #2253 *O 1 Tom Thumb Sterilisation #22531 *O 1 Tom Thumb Sterilisation Tomb Thumb Sterility
8.6			#22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #15461 *M 1 Tom Thumb Packaging Trials and validation #7724 *M 1 Tom Thumb Packaging Trials and validation Packagine TT480 #2245 *M 1 Tom Thumb Packaging Trials and validation Packaging Photographs 2004 #2244 *M 1 Tom Thumb Packaging Trials and validation Packaging Trial 2004 #7726 *M 1 Tom Thumb Packaging Trials and validation TT495

General Requirement	Applied Standards	Notes	Files
8.7			#22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #11743 *F 7 Tom Thumb Labels Part number to Label #20970 *F 7 Tom Thumb Labels Top Box Sticker example #2253 *O 1 Tom Thumb Sterilisation #22531 *O 1 Tom Thumb Sterilisation Tomb Thumb Sterility
9.1			#22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #22898 *F 4 Tom Thumb Description of Accessories Background Notes for Tom Thumb Accessories #1663 *F 4 Tom Thumb Description of Accessories silicone adaptor #11732 *F 5 Tom Thumb Instructions for Use User Manual #8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15 #11747 *F 7 Tom Thumb Labels Caution Label 0390018 Top Block

General Requirement	Applied Standards	Notes	Files
9.2			#22375 CHART 35 Products On Market Risk Management Plan Post Market Surveillance #22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #22902 *Y 1 Tom Thumb Design Input Device History Background Notes for Tom Thumb Design SN #2362 *Y 1 Tom Thumb Design Input Device History Device Theory 2005 #22906 *Y 1 Tom Thumb Design Input Device History Tom Thumb Design #2176 *D 4 *D 5 Tom Thumb EMC rationale #2183 *E 4 Tom Thumb EN ISO 14971:2001 Annex A #8489 *E 5 Tom Thumb EN ISO 14971:2001 Annex D #2970 *E 4 Tom Thumb EN1998 Risk Analysis #23843 *E 3 Tom Thumb Risk analysis reports Risk assessment #23831 *E 3 *E 11 Tom Thumb Risk analysis reports Risk analysis 2017
9.3		Manufactured Out Of Brass No Combustible Parts	

General Requirement	Applied Standards	Notes	Files
10.1			#22902 *Y 1 Tom Thumb Design Input Device History Background Notes for Tom Thumb Design SN #22906 *Y 1 Tom Thumb Design Input Device History Tom Thumb Design #3007 *T 1 Tom Thumb Specifications of Materials 1997 Therapy Equipment 3 001 #3008 *T 1 Tom Thumb Specifications of Materials 1997 Wika #3009 *T 1 Tom Thumb Specifications of Materials 1997 Wika 4 001 #2247 *M 3 Tom Thumb Specifications Technical Specification 1997 #13680 *M 3 *T 2 Tom Thumb Specifications Temperature Range #23511 *M 3 *Y 10 Tom Thumb Specifications Wika quote gauge cmH2o
10.2		Clear Display Dial	#15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15
10.3			
11.1			
11.2			
11.2 i			#9456 *Z 12 Generic CE File Attached to All Ionising Radiation None
11.2 2			#9456 *Z 12 Generic CE File Attached to All Ionising Radiation None

General Requirement	Applied Standards	Notes	Files
11.3			#9456 *Z 12 Generic CE File Attached to All Ionising Radiation None
11.3 1			#9456 *Z 12 Generic CE File Attached to All Ionising Radiation None
11.4			#11732 *F 5 Tom Thumb Instructions for Use User Manual #15570 *F 5 Tom Thumb Instructions for Use User Manual 0310027 #8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15
11.4 1			#9456 *Z 12 Generic CE File Attached to All Ionising Radiation None
11.5			#9456 *Z 12 Generic CE File Attached to All Ionising Radiation None
11.5 1			#9456 *Z 12 Generic CE File Attached to All Ionising Radiation None

General Requirement	Applied Standards	Notes	Files
11.5 2			#9456 *Z 12 Generic CE File Attached to All Ionising Radiation None
11.5 3			#9456 *Z 12 Generic CE File Attached to All Ionising Radiation None
12			
12.1 i			#7440 *Y 19 Tom Thumb Software
12.1 ii			#7440 *Y 19 Tom Thumb Software
12.2			#14046 *F 1 Tom Thumb Description of Device
12.3		Safety Does Not Depend On The Gas Supply.Doc 14046 Description Of The Device. Use Of The Device Relies On The User Observing The Gas Flow And Resultant Pressure. Training Is Available Doc 15644User Manuals E.g. Doc 15572Short Form;- plasticised Version To Hang On The Tom Thumb Doc8506Training Is Usually Implemented By The Hospitals Who Set Individual Protocols.	

General Requirement	Applied Standards	Notes	Files
12.4			
12.5			#2176 *D 4 *D 5 Tom Thumb EMC rationale
12.6			#2183 *E 4 Tom Thumb EN ISO 14971:2001 Annex A #8489 *E 5 Tom Thumb EN ISO 14971:2001 Annex D #2970 *E 4 Tom Thumb EN1998 Risk Analysis #23843 *E 3 Tom Thumb Risk analysis reports Risk assessment #23831 *E 3 *E 11 Tom Thumb Risk analysis reports Risk analysis 2017
12.7			
12.7 1			
12.7 2			
12.7 3			
12.7 4			
12.7 5			

General Requirement	Applied Standards	Notes	Files
12.8			#22375 CHART 35 Products On Market Risk Management Plan Post Market Surveillance #22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #22494 *U 1 Tom Thumb Purchase specifications Flowmeter #22490 *U 1 Tom Thumb Purchase specifications Wika 6111.10 gauge #23843 *E 3 Tom Thumb Risk analysis reports Risk assessment
12.8 1			#14046 *F 1 Tom Thumb Description of Device #11732 *F 5 Tom Thumb Instructions for Use User Manual #15570 *F 5 Tom Thumb Instructions for Use User Manual 0310027 #8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15 #22494 *U 1 Tom Thumb Purchase specifications Flowmeter

General Requirement	Applied Standards	Notes	Files
12.8 2			#14046 *F 1 Tom Thumb Description of Device #11732 *F 5 Tom Thumb Instructions for Use User Manual #15570 *F 5 Tom Thumb Instructions for Use User Manual 0310027 #8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15
12.9			#11744 *F 7 Tom Thumb Labels 0390010 Adjustable Value Sticker #11747 *F 7 Tom Thumb Labels Caution Label 0390018 Top Block #11743 *F 7 Tom Thumb Labels Part number to Label

General Requirement	Applied Standards	Notes	Files
13			#11732 *F 5 Tom Thumb Instructions for Use User Manual #15570 *F 5 Tom Thumb Instructions for Use User Manual 0310027 #8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15 #11744 *F 7 Tom Thumb Labels 0390010 Adjustable Value Sticker #11745 *F 7 Tom Thumb Labels 0390015 Front Block Logo Sticker #11748 *F 7 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge #11746 *F 7 Tom Thumb Labels 0390017 Front of Gauge Sticker #11747 *F 7 Tom Thumb Labels Caution Label 0390018 Top Block #15638 *F 7 *Y 11 Tom Thumb Labels Original labels #11743 *F 7 Tom Thumb Labels Part number to Label #11740 *F 7 Tom Thumb Labels Serial TT480 #2204 *F 7 Tom Thumb Labels Tomb Thumb Infant Resuscitator

General Requirement	Applied Standards	Notes	Files
			#20970 *F 7 Tom Thumb Labels Top Box Sticker example #11741 *F 7 Tom Thumb Labels TT490 Serial #11742 *F 7 Tom Thumb Labels TT491 Serial #2254 *R1 *F 7 Tom Thumb Parts List Adj label 04

General Requirement	Applied Standards	Notes	Files
13.1			#14046 *F 1 Tom Thumb Description of Device #15570 *F 5 Tom Thumb Instructions for Use User Manual 0310027 #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15 #11744 *F 7 Tom Thumb Labels 0390010 Adjustable Value Sticker #11747 *F 7 Tom Thumb Labels Caution Label 0390018 Top Block #5922 *F 7 Tom Thumb Labels mediprema labels #11743 *F 7 Tom Thumb Labels Part number to Label #11740 *F 7 Tom Thumb Labels Serial TT480 #20970 *F 7 Tom Thumb Labels Top Box Sticker example
13.2			#11744 *F 7 Tom Thumb Labels 0390010 Adjustable Value Sticker #11747 *F 7 Tom Thumb Labels Caution Label 0390018 Top Block #11743 *F 7 Tom Thumb Labels Part number to Label #20970 *F 7 Tom Thumb Labels Top Box Sticker example

General Requirement	Applied Standards	Notes	Files
13.3			
13.3 a			#11748 *F 7 Tom Thumb Labels 0390016 Address Sticker Round outside Gauge #11743 *F 7 Tom Thumb Labels Part number to Label
13.3 b			#11740 *F 7 Tom Thumb Labels Serial TT480 #20970 *F 7 Tom Thumb Labels Top Box Sticker example #11741 *F 7 Tom Thumb Labels TT490 Serial #11742 *F 7 Tom Thumb Labels TT491 Serial
13.3 c			
13.3 d			#11743 *F 7 Tom Thumb Labels Part number to Label #11740 *F 7 Tom Thumb Labels Serial TT480 #20970 *F 7 Tom Thumb Labels Top Box Sticker example #11741 *F 7 Tom Thumb Labels TT490 Serial #11742 *F 7 Tom Thumb Labels TT491 Serial
13.3 e			
13.3 f			
13.3 g			

General Requirement	Applied Standards	Notes	Files
13.3 h			
13.3 i			#20970 *F 7 Tom Thumb Labels Top Box Sticker example
13.3 j			
13.3 k			#11732 *F 5 Tom Thumb Instructions for Use User Manual #15570 *F 5 Tom Thumb Instructions for Use User Manual 0310027 #8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15 #11747 *F 7 Tom Thumb Labels Caution Label 0390018 Top Block #11743 *F 7 Tom Thumb Labels Part number to Label
13.3 l			#20970 *F 7 Tom Thumb Labels Top Box Sticker example
13.3 m			#2253 *O 1 Tom Thumb Sterilisation

General Requirement	Applied Standards	Notes	Files
13.3 n			#8315 *Z 13 Human Blood & derivatives Statement of non use
13.4			#14046 *F 1 Tom Thumb Description of Device #11732 *F 5 Tom Thumb Instructions for Use User Manual #15570 *F 5 Tom Thumb Instructions for Use User Manual 0310027 #8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15
13.5		Serial Numbers	

General Requirement	Applied Standards	Notes	Files
13.6			#11732 *F 5 Tom Thumb Instructions for Use User Manual #15570 *F 5 Tom Thumb Instructions for Use User Manual 0310027 #8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15
13.6 a			
13.6 b			

General Requirement	Applied Standards	Notes	Files
13.6 c			#22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #15621 *F 4 Tom Thumb Description of Accessories #15634 *F 4 Tom Thumb Description of Accessories #2188 *F 4 Tom Thumb Description of Accessories Datex-Ohmeda Giraffe Incubator #1663 *F 4 Tom Thumb Description of Accessories silicone adaptor #11732 *F 5 Tom Thumb Instructions for Use User Manual #15570 *F 5 Tom Thumb Instructions for Use User Manual 0310027 #8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15

General Requirement	Applied Standards	Notes	Files
13.6 d			#11732 *F 5 Tom Thumb Instructions for Use User Manual #15570 *F 5 Tom Thumb Instructions for Use User Manual 0310027 #8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15 #2209 *G 1 Tom Thumb Maintenance #15008 *G 1 Tom Thumb Maintenance Parts required for Annual Service of TT480 and TT490 #2212 *G 1 Tom Thumb Maintenance Service & Care of Tom Thumb 1994
13.6 e			
13.6 f			
13.6 g			

General Requirement	Applied Standards	Notes	Files
13.6 h			#22486 *M 1 *O 1 *E 6 *G 4 *F 4 *Y 0 *E 3 *D 7 *C 2 Tom Thumb Background Notes for Tom Thumb #11732 *F 5 Tom Thumb Instructions for Use User Manual #15570 *F 5 Tom Thumb Instructions for Use User Manual 0310027 #8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15 #2253 *O 1 Tom Thumb Sterilisation #22531 *O 1 Tom Thumb Sterilisation Tomb Thumb Sterility
13.6 i			
13.6 j			#9456 *Z 12 Generic CE File Attached to All Ionising Radiation None
13.6 k			

General Requirement	Applied Standards	Notes	Files
13.6 l			#2176 *D 4 *D 5 Tom Thumb EMC rationale #11732 *F 5 Tom Thumb Instructions for Use User Manual #15570 *F 5 Tom Thumb Instructions for Use User Manual 0310027 #8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15
13.6 m			
13.6 n			#11732 *F 5 Tom Thumb Instructions for Use User Manual #15570 *F 5 Tom Thumb Instructions for Use User Manual 0310027 #8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15 #15572 *F 5 *F 6 Tom Thumb Instructions for Use / User Manual TT490-15

General Requirement	Applied Standards	Notes	Files
13.6 o			#8315 *Z 13 Human Blood & derivatives Statement of non use #13136 *Z 8 Medicinal Substances None #13135 *Z 10 No Animal Tissues No Animal Substances
13.6 p			#13680 *M 3 *T 2 Tom Thumb Specifications Temperature Range #23511 *M 3 *Y 10 Tom Thumb Specifications Wlka quote gauge cmH2o
13.6 q			#11732 *F 5 Tom Thumb Instructions for Use User Manual #15570 *F 5 Tom Thumb Instructions for Use User Manual 0310027 #8512 *F 5 *F 4 Tom Thumb Instructions for Use User Manual NeoPEEP #15571 *F 5 Tom Thumb Instructions for Use User Manual TT480 #12211 *F 5 Tom Thumb Instructions for Use User Manual TT495-15