Post market surveillance risk assesment re-evaluation

VIAMED

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
26 / 08 / 14

VIAMED

- Stock References Review
- Supplier Review
- Sales Review
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- Design Changes Review
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- Labels Review
- Document Updates Review
- Internal Issues Review
- Clinical / FDA Incidents online search
- Risk ISO 14971 : 2012 Review

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.
0310098	Tom Thumb Oxygen Flow.
0310099	Tom Thumb Oxygen Vent.
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
0330215	Clamp Spacer
0330216	Screws For Clamp
0330217	Oxygen hose 1m. C/W indirect probe &

Stock Reference	Description
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

Comments on Stock references review:

All parts are correct

Supplier Review

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0320221	Pole Clamp without slide bracket.	00007317	Inspiration Healthcare Limited	A
0320103	Tom Thumb Rectangular Mounting Block.	00009022	Tanda Engineering Ltd	A
0330185	Wing Nut Screw Black 25mm Thread	00009032	R & L Enterprises Ltd	B
0330190	Universal clamp - 44mm horizontal	00009032	R & L Enterprises Ltd	B
0330191	Clamp Spacer	00009032	R & L Enterprises Ltd	B
0330242	Medirail Mounting Bracket	00009032	R & L Enterprises Ltd	B
0330216	Screws For Clamp	00009061	Farnell	A
0330234	Adjustable Valve Side Screw	00009073	Modern Screws	B
0330243	Adjustable Valve Side Screw. Bag 100	00009073	Modern Screws	B
0330193	Pressure gauge: 63mm dial -5 to +60 cmWG	00009097	Gauges North West Ins. - GNW	Needs Grading
0330210	Precision Valve	00009117	JNK Tooling	B
0330211	Adjustable Valve	00009117	JNK Tooling	B
0330224	Precision Valve Body	00009117	JNK Tooling	B
0330227	Precision/Adjustable Valve Seat	00009117	JNK Tooling	B
0330228	Precision Valve Adjustable Screw	00009117	JNK Tooling	B
0330230	Adjustable Valve Screw	00009117	JNK Tooling	B
0330234	Adjustable Valve Side Screw	00009117	JNK Tooling	B
0330235	Inlet Restrictor	00009117	JNK Tooling	B
0330207	Blanking Bolt	00009123	RS Components Ltd	B
0330213	O Ring Thick	00009123	RS Components Ltd	B
0330214	O Ring Thin	00009123	RS Components Ltd	B
0330216	Screws For Clamp	00009123	RS Components Ltd	B
0330220	Fomblin OT20 Grease 100g tube	00009123	RS Components Ltd	B
0330221	Lock Tight	00009123	RS Components Ltd	B
0330296	Blanking Bolt	00009123	RS Components Ltd	B
0320060	Flowmeter (Oxygen) 0-15 Lpm.	00009150	Therapy Equipment Ltd	A
0330030	Dovetail (male)	00009150	Therapy Equipment Ltd	A
0330055	Universal clamp - 44mm horizontal	00009150	Therapy Equipment Ltd	A
0330204	Flowmeter (air) 0-15 Lpm	00009150	Therapy Equipment Ltd	A
0330212	Gauge Seal	00009150	Therapy Equipment Ltd	A
0330217	Oxygen hose 1m. C/W indirect probe &	00009150	Therapy Equipment Ltd	A
0330218	Oxygen Hose 3m. C/W indirect probe &	00009150	Therapy Equipment Ltd	A
0330250	Oxygen hose 1.5m. C/W DIN fitting:	00009150	Therapy Equipment Ltd	A
0330251	Oxygen hose 3.0m. C/W DIN fitting:	00009150	Therapy Equipment Ltd	A
0330263	Oxygen Hose 2m. C/W indirect probe &	00009150	Therapy Equipment Ltd	A
0330268	Air Hose 3m. C/W indirect probe &	00009150	Therapy Equipment Ltd	A
3210011	NeoPEEP neonatal single patient use	00009602	Bunzl Healthcare	C
3210071	Single use silicone round facemask	00009602	Bunzl Healthcare	C
3210011	NeoPEEP neonatal single patient use	00009721	Marshall Products Limited	B
3210071	Single use silicone round facemask	00009721	Marshall Products Limited	B
0330200	TT460 MAIN Body Block	00010160	KSJ Engineering Limited	B
0330201	TT480/490 MAIN Body Block	00010160	KSJ Engineering Limited	B

Stock Reference	Description	Supplier A/C	Supplier Name	Rating
0330202	TT495 MAIN Body Block	00010160	KSJ Engineering Limited	B
0330205	Flowmeter Meter Bolt	00010160	KSJ Engineering Limited	B
0330206	Blocking Bolt And Nut	00010160	KSJ Engineering Limited	B
0330208	Inlet 10 mm	00010160	KSJ Engineering Limited	B
0330209	Outlet 15mm	00010160	KSJ Engineering Limited	B
0330215	Clamp Spacer	00010160	KSJ Engineering Limited	B
0330241	TT480/490 MAIN Body Block	00010160	KSJ Engineering Limited	B
0330246	Blocking Bolt And Nut	00010160	KSJ Engineering Limited	B
0330248	Inlet 10 mm	00010160	KSJ Engineering Limited	B
0330249	Outlet 15mm	00010160	KSJ Engineering Limited	B
0330295	Outlet 10mm do not use	00010160	KSJ Engineering Limited	B
0330203	Pressure gauge for `Tom Thumb` Infant	00010395	Wika Instruments Ltd	B
0330236	Replacement Gauge Face.	00010395	Wika Instruments Ltd	B
0330200	TT460 MAIN Body Block	00010725	MAJ Hi-Spec Ltd	B
0330201	TT480/490 MAIN Body Block	00010725	MAJ Hi-Spec Ltd	B
0330202	TT495 MAIN Body Block	00010725	MAJ Hi-Spec Ltd	B
0330205	Flowmeter Meter Bolt	00010725	MAJ Hi-Spec Ltd	B
0330206	Blocking Bolt And Nut	00010725	MAJ Hi-Spec Ltd	B
0330207	Blanking Bolt	00010725	MAJ Hi-Spec Ltd	B
0330208	Inlet 10 mm	00010725	MAJ Hi-Spec Ltd	B
0330209	Outlet 15mm	00010725	MAJ Hi-Spec Ltd	B
0330219	Right Angle For Hose	00010770	Chelmer Pneumatics Ltd	B
0120140	Adapter 15mm I.D. - 15mm I.D	00011844	Instrumentation Industries Inc	B
0330222	Precision Valve Spring	00012028	Harlow Springs Limited	B
0330223	Adjustable Valve Spring	00012028	Harlow Springs Limited	B
0330300	Key Ring chain 1 inch ball	00012395	Seton	B

Comments on Suppliers:

Suppliers are correct,
Gauges North West Ins are new supplier, we`re currently evaluating replace ment gauges to the Wika gauge.

Sales Information

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
0310027	Tom Thumb Infant Resuscitator (Air).							
0310029	Tom Thumb Infant Resuscitator (Air).							
0310030	Tom Thumb Infant Resuscitator.	131	59	80	121	259	123	107
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).		4		1		1	2
0310072	Tom Thumb Infant Resuscitator.	18						
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).	2						
0310093	Tom Thumb Infant Resuscitator.				2			
0310094	Tom Thumb Infant Resuscitator.				8		9	
0310098	Tom Thumb Oxygen Flow.							
0310099	Tom Thumb Oxygen Vent.		5				1	1
0320102	Tom Thumb Rectangular Mounting Block.							
0320103	Tom Thumb Rectangular Mounting Block.	1						
0330185	Wing Nut Screw Black 25mm Thread							
0330190	Universal clamp - 44mm horizontal						2	50
0330191	Clamp Spacer						1	
0330193	Pressure gauge: 63mm dial -5 to +60 cmWG							
0330200	TT460 MAIN Body Block							
0330201	TT480/490 MAIN Body Block				1			
0330202	TT495 MAIN Body Block						1	
0330203	Pressure gauge for `Tom Thumb` Infant	17	30	20	13	10	21	7
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	
0330209	Outlet 15mm	5						
0330210	Precision Valve		2	2	4		3	
0330211	Adjustable Valve	2		2	1	2	3	
0330212	Gauge Seal	34	29	55	31	40	28	20
0330213	O Ring Thick	14	40	13	77	8	34	183
0330214	O Ring Thin	204	235	135	358	48	227	117
0330215	Clamp Spacer	4	1					
0330216	Screws For Clamp	28		4				
0330217	Oxygen hose 1m. C/W indirect probe &		8	8			6	10

Stock Reference	Description	2008	2009	2010	2011	2012	2013	2014
0330218	Oxygen Hose 3m. C/W indirect probe &	6	28	13	15	2	7	17
0330219	Right Angle For Hose			1	2			
0330220	Fomblin OT20 Grease 100g tube							
0330221	Lock Tight							
0330222	Precision Valve Spring					1		
0330223	Adjustable Valve Spring					2		
0330224	Precision Valve Body							
0330225	Precision/Adjustable Valve Seating							
0330227	Precision/Adjustable Valve Seat			1		2	1	
0330228	Precision Valve Adjustable Screw							
0330229	Adjustable Valve Body						1	
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			5				
0330236	Replacement Gauge Face.	5	9	17	6	5	13	5
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 &						3	8
0330268	Air Hose 3m. C/W indirect probe &							
0330291	Inlet 10mm Thumbelina Inlet							
0330292	Outlet 15mm Thumbelina							
0330295	Outlet 10mm do not use		2					
0330296	Blanking Bolt							
0330297	Clamp Spacer - dove tailed.			5				
0330300	Key Ring chain 1 inch ball							

Comments on Sales Information:

Units still selling

Countries Review

Country	2008	2009	2010	2011	2012	2013	2014
B Belgium	[X]	[X]			[X]	[X]	
BRA Brazil							
C China							[X]
CAN Canada		[X]					
CZ Czech Republic							[X]
F France	[X]	[X]	[X]	[X]	[X]	[X]	[X]
IN India						[X]	
IT Italy			[X]				
MA Malaysia		[X]					
NE Netherlands							
NG Nigera							[X]
RU Russia		[X]	[X]	[X]	[X]	[X]	[X]
SAU Saudi Arabia					[X]	[X]	
SWI Switzerland		[X]					
T Turkey		[X]			[X]		
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]

Comments on Sales to Countries:

China, Czech Republic, Nigera new countries

Comments on Risks with Sales to Countries:

No risks identified with the new countrys

Returns Review

Stock Reference	Fault	2008	2009	2010	2011	2012	2013	2014
0310030	Adjusted factory set valves						3	
0310030	Converted to TT480	1				1		
0310030	Damaged Pressure Gauge	2	4	2				1
0310030	n/a							
0310030	No Fault Found		1					
0310030	No Fault Return to Stock							
0310030	Replace gauge and service							1
0310030	Serviced	2	3					
0310030	Serviced / adjusted factory set valves		2	1		3	11	6
0310030	Tested		1					
0310032	Adjusted factory set valves			1				
0310032	Calibrated Gauge		1					
0310032	Converted to TT480					1		
0310032	Damaged Pressure Gauge			1				
0310032	Serviced	1						
0310032	Serviced / adjusted factory set valves		1	2			1	
0310032	Tested		1				1	
0310033	Serviced							
0310034	Adjusted factory set valves		2					
0310034	Damaged Pressure Gauge	1						
0310034	Serviced						1	
0310034	Serviced / adjusted factory set valves			2	1	1	2	
0310034	Unchecked - Returned to Stock							
0310080	Replace gauge and service							1
0310094	Converted to TT480						9	
0310098	Serviced / adjusted factory set valves							1
0330217	Unchecked - Returned to Stock							

Comments on Returns:

Returns consist of Services, tests, and Conversions to a different model of Tom Thumb.
Only real fault identified is broke gauge(s).

Comments on Risks with Returns and Potential Re-work:

There are no risks with reworking / repairing / Servicing Tom thumbs.

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

No design changes have taken place

Comments on Risks with Design Changes:

not applicable - no changes

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
13047	Tom Thumb Instructions for Use User Manual French	14/10/13
12212	Tom Thumb Instructions for Use User Manual TT480	30/11/12
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
8503	Tom Thumb Instructions for Use / User Manual TT490-15	06/07/11
5107	Instructions For Use Tom Thumb TT480	23/02/09

Comments on User Instructions:

User instructions converted to French

Comments on Risks User Instructions:

No risks to user instructions

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Document ID	Description	Date Added/Updated
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
2204	Tom Thumb Labels Tomb Thumb Infant Resuscitator	19/06/07

Comments on Labels:

no changes to the labels

Comments on Risks Labels:

No risks identified with the labels

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
14188	Tom Thumb OES (OEM) CE Certificate Wika ISO 9001:2008	26/08/14
14099	Tom Thumb Drawings 0330193 dial artwork	15/07/14
14097	Tom Thumb Purchase specifications GNW Instrumentation - Tom Thum...	10/07/14
14091	Tom Thumb Possible replacement Parts Specification Sheets 033019...	03/07/14
14046	Tom Thumb Description of Device	10/06/14
14011	Tom Thumb Clinical Trials Reports	04/06/14
14007	Tom Thumb Design Input Device History IMI positive pressure ven...	04/06/14
14006	Tom Thumb Quotations IMI Pre Tom Thumb	04/06/14
13680	Tom Thumb Specifications Temperature Range	06/05/14
13654	Tom Thumb Competitor Instructions for use for similar products F...	22/04/14
13190	Service Manual V1.8 TT480 Tom Thumb	02/12/13
13136	Generic CE File Attached to All Medicinal Substances None	31/10/13
13135	No Animal Tissues No Animal Substances	31/10/13
13047	Tom Thumb Instructions for Use User Manual French	14/10/13
13005	Tom Thumb EC Declaration of Conformance (scanned signed)	23/09/13
12820	Tom Thumb Post Market Surveillance	31/07/13

Comments on Document Changes:

Specifications to the possible replacement gauge, supplier ISO certificates and the Yealry PMS Documents updated

Comments on Risks with Document Changes:

No risks identified with the newer documentation

Internal Issues Review

Number of Issues reviewed: 25

Issue ID	Subject
49369	Returned Items SOR598
50015	Web Site Question ID 190
48262	Tom Thumb production status
47328	PAQ for resus cabinet required asap
42381	Declartions of Conformity required
42380	Declartions of Conformity required
46114	Add items
48113	0330033 suction hose price change
51049	0330193 dial artwork
50477	GNW Instrumentation - Tom Thumb pressure gauge
49177	Pressure gauges
51551	Air/oxygen blender price list requires updating
50928	JSC order
44936	POR09224 0330236 Delivery date Change
44935	POR09224 0330236 Delivery date Change
44790	POR09224 0330236 Delivery date Change
50906	0330210 & 0330211
48896	
48112	Tom Thumb parts stock review
42523	0330190 0330191 JSC Serceinstrument
51784	Resus cabinet service visit - Blackburn Birthing Centre
51783	Resus cabinet service visit - Blackburn Birthing Centre
50933	Pressure gauges for Thom Thumbs.
50932	Pressure gauges for Thom Thumbs.
50931	Pressure gauges for Thom Thumbs.

Comments on Issues:

Mainly stock Issues,
some issues on the testing of the GNW guage. No problems in the Issues identified

Comments on Risks with Issues:

No risks identified in the Issues system

Clinical / FDA Incidents online search

Clinical Investigation online review

Do any of the Results indicate a Risk / Problem : No
Do any of the Results indicate outdated Technology : No
Comments on Clinical Search :

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem : No
Do any of the Results indicate outdated Technology : No
Comments on Clinical Search :

Risk ISO 14971 : 2012 Review

	Negligible	Minor	Serious	Critical	Catastrophic
Improbable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable
Remote	Acceptable	Acceptable	Acceptable	Unacceptable	Unacceptable
Occasinal	Acceptable	Acceptable	Acceptable	Unacceptable	Unacceptable
Probable		Unacceptable	Unacceptable	Unacceptable	Unacceptable
Frequent	Unacceptable	Unacceptable	Unacceptable	Unacceptable	Unacceptable

C.2.1 What is the intended use and how is the medical device to be used

[ID]	Reference Question	Applys	Risk	Probability	Overall
1	what is the medical device`s role relative to diagnosis,	No	---	---	n/a
2	what is the medical device`s role relative to prevention	No	---	---	n/a
3	what is the medical devices role relative to monitoring	No	---	---	n/a
4	what is the medical devices role relative to treatment	No	---	---	n/a
5	what is the medical devices role relative to alleviation of disease	No	---	---	n/a
6	what is the medical devices role relative to compensation for injury or handicap	No	---	---	n/a
7	what is the medical devices role relative to replacement or modification of anatomy	No	---	---	n/a
8	what is the medical devices role relative to control of conception	No	---	---	n/a
9	does the medical device sustain life	No	---	---	n/a
10	does the medical device support life	Yes	Minor	Remote	Acceptable
11	is special intervention necessary in the case of failure of the medical device	Yes	Serious	Remote	Acceptable
330	What are the indications for use e.g. patient population	No	---	---	n/a

C.2.10 Is the medical device intended to modify the patient environment

[ID]	Reference Question	Applys	Risk	Probability	Overall
56	Factors that should be considered include temperature	No	---	---	n/a
57	Factors that should be considered include humidity	No	---	---	n/a
58	Factors that should be considered include atmospheric gas composition	No	---	---	n/a
59	Factors that should be considered include pressure	Yes	Critical	Remote	Acceptable
60	Factors that should be considered include light	No	---	---	n/a

C.2.11 Are measurements taken

[ID]	Reference Question	Applys	Risk	Probability	Overall
61	Factors that should be considered include the variables measured and the accuracy and the precision of the measurement results.	No	---	---	n/a

C.2.12 Is the medical device interpretative

[ID]	Reference Question	Applys	Risk	Probability	Overall
62	Factors that should be considered include whether conclusions are presented by the medical device from input or acquired data	No	---	---	n/a
63	Factors that should be considered include whether conclusions are presented by the medical device from the algorithms used	No	---	---	n/a
64	Factors that should be considered include whether conclusions are presented by the medical device from the confidence limits	No	---	---	n/a
65	Factors that should be considered include whether conclusions are presented by the medical device. Special attention should be given to unintended applications of the data or algorithm	No	---	---	n/a

C.2.13 Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies

[ID]	Reference Question	Applys	Risk	Probability	Overall
66	Factors that should be considered include identifying any other medical devices	No	---	---	n/a
67	Factors that should be considered include identifying any other medicines	No	---	---	n/a
68	Factors that should be considered include identifying any other medical technologies that can be involved	No	---	---	n/a

C.2.14 Are there unwanted outputs of energy or substances

[ID]	Reference Question	Applys	Risk	Probability	Overall
69	Energy-related factors that should be considered include vibration,	No	---	---	n/a
70	Energy-related factors that should be considered include heat,	No	---	---	n/a
71	Energy-related factors that should be considered include radiation,	No	---	---	n/a
72	Energy-related factors that should be considered include noise,	No	---	---	n/a
73	Energy-related factors that should be considered include ionizing radiation,	No	---	---	n/a
74	Energy-related factors that should be considered include non-ionizing radiation,	No	---	---	n/a
75	Energy-related factors that should be considered include ultraviolet/ radiation,	No	---	---	n/a
76	Energy-related factors that should be considered include visible radiation,	No	---	---	n/a
77	Energy-related factors that should be considered include infrared radiation,	No	---	---	n/a
78	Energy-related factors that should be considered include contact temperatures	No	---	---	n/a
79	Energy-related factors that should be considered include leakage currents	No	---	---	n/a
80	Energy-related factors that should be considered include electric fields	No	---	---	n/a
81	Energy-related factors that should be considered include magnetic fields	No	---	---	n/a
82	Substance-related factors that should be considered include substances used in manufacturing	No	---	---	n/a

[ID]	Reference Question	Applys	Risk	Probability	Overall
83	Substance-related factors that should be considered include substances used in cleaning	No	---	---	n/a
84	Substance-related factors that should be considered include substances used in testing	No	---	---	n/a
85	Other substance-related factors that should be considered include discharge of chemicals	No	---	---	n/a
86	Other substance-related factors that should be considered include waste products	No	---	---	n/a
87	Other substance-related factors that should be considered include body fluids	No	---	---	n/a

C.2.15 Is the medical device susceptible to environmental influences

[ID]	Reference Question	Applys	Risk	Probability	Overall
88	Factors that should be considered include the operational environment	No	---	---	n/a
89	Factors that should be considered include the transport environment	No	---	---	n/a
90	Factors that should be considered include the storage environment	No	---	---	n/a
91	Factors that should be considered include light	No	---	---	n/a
92	Factors that should be considered include temperature	No	---	---	n/a
93	Factors that should be considered include humidity	No	---	---	n/a
94	Factors that should be considered include vibrations	No	---	---	n/a
95	Factors that should be considered include spillage	No	---	---	n/a
96	Factors that should be considered include susceptibility to variations in power	No	---	---	n/a
97	Factors that should be considered include susceptibility to variations in cooling supplies	No	---	---	n/a
98	Factors that should be considered include susceptibility to variations in electromagnetic interference	No	---	---	n/a

C.2.16 Does the medical device influence the environment

[ID]	Reference Question	Applys	Risk	Probability	Overall
99	Factors that should be considered include the effects on power and cooling supplies	No	---	---	n/a
100	Factors that should be considered include the emission of toxic materials	No	---	---	n/a
101	Factors that should be considered include the generation of electromagnetic disturbance	No	---	---	n/a

C.2.17 Are there essential consumables or accessories associated with the medical device

[ID]	Reference Question	Applys	Risk	Probability	Overall
102	Factors that should be considered include specifications for such consumables	Yes	Minor	Remote	Acceptable
103	Factors that should be considered include specifications for such accessories	Yes	Minor	Remote	Acceptable

[ID]	Reference Question	Applys	Risk	Probability	Overall
104	Factors that should be considered include any restrictions placed upon users in their selection of consumables.	No	---	---	n/a
105	Factors that should be considered include any restrictions placed upon users in their selection of accessories.	Yes	Serious	Remote	Acceptable

C.2.18 Is maintenance or calibration necessary

[ID]	Reference Question	Applys	Risk	Probability	Overall
106	Factors that should be considered include whether maintenance or calibration are to be carried out by the operator	No	---	---	n/a
107	Factors that should be considered include whether maintenance or calibration are to be carried out by the user	No	---	---	n/a
108	Factors that should be considered include whether maintenance or calibration are to be carried out by the specialist	Yes	Minor	Remote	Acceptable
109	Factors that should be considered include are special substances or equipment necessary for proper maintenance	No	---	---	n/a
110	Factors that should be considered include are special substances or equipment necessary for proper calibration	Yes	Minor	Remote	Acceptable

C.2.19 Does the medical device contain software

[ID]	Reference Question	Applys	Risk	Probability	Overall
111	Factors that should be considered include whether software is intended to be installed	No	---	---	n/a
112	Factors that should be considered include whether software is intended to be verified	No	---	---	n/a
113	Factors that should be considered include whether software is intended to be modified	No	---	---	n/a
114	Factors that should be considered include whether software is intended to be exchanged	No	---	---	n/a

C.2.2 Is the medical device intended to be implanted

[ID]	Reference Question	Applys	Risk	Probability	Overall
12	Factors that should be considered include the location of implantation,	No	---	---	n/a
13	Factors that should be considered include the characteristics of the patient population	No	---	---	n/a
14	Factors that should be considered include the characteristics of the patient age	No	---	---	n/a
15	Factors that should be considered include the characteristics of the patient weight	No	---	---	n/a
16	Factors that should be considered include the characteristics of the patient physical activity	No	---	---	n/a
17	Factors that should be considered include the effect of ageing on implant performance	No	---	---	n/a

[ID]	Reference Question	Applys	Risk	Probability	Overall
18	Factors that should be considered include the expected lifetime of the implant	No	---	---	n/a
19	Factors that should be considered include the reversibility of the implantation	No	---	---	n/a

C.2.20 Does the medical device have a restricted shelf-life

[ID]	Reference Question	Applys	Risk	Probability	Overall
115	Factors that should be considered include labelling	No	---	---	n/a
116	Factors that should be considered include indicators	No	---	---	n/a
117	Factors that should be considered include disposal of such medical devices	No	---	---	n/a

C.2.21 Are there any delayed or long-term use effects

[ID]	Reference Question	Applys	Risk	Probability	Overall
118	Factors that should be considered include ergonomic effects	No	---	---	n/a
119	Factors that should be considered include cumulative effects	No	---	---	n/a

C.2.22 To what mechanical forces will the medical device be subjected

[ID]	Reference Question	Applys	Risk	Probability	Overall
120	Factors that should be considered include whether the forces to which the medical device will be subjected are under the control of the user	No	---	---	n/a
121	Factors that should be considered include whether the forces to which the medical device will be subjected are controlled by interaction with other persons	No	---	---	n/a

C.2.23 What determines the lifetime of the medical device

[ID]	Reference Question	Applys	Risk	Probability	Overall
122	Factors that should be considered include ageing	No	---	---	n/a
123	Factors that should be considered include battery depletion.	No	---	---	n/a

C.2.24 Is the medical device intended for single use

[ID]	Reference Question	Applys	Risk	Probability	Overall
124	Factors that should be considered include does the medical device self-destruct after use	No	---	---	n/a
125	Factors that should be considered include Is it obvious that the device has been used	No	---	---	n/a

C.2.25 Is safe decommissioning or disposal of the medical device necessary

[ID]	Reference Question	Applys	Risk	Probability	Overall
126	Factors that should be considered include the waste products that are generated during the disposal of the medical device itself	No	---	---	n/a
127	Factors that should be considered include does it contain toxic material	No	---	---	n/a
128	Factors that should be considered include does it contain hazardous material	No	---	---	n/a
129	Factors that should be considered include is the material recyclable	Yes	Minor	Remote	Acceptable

C.2.26 Does installation or use of the medical device require special training or special skills

[ID]	Reference Question	Applys	Risk	Probability	Overall
130	Factors that should be considered include the novelty of the medical device	No	---	---	n/a
131	Factors that should be considered include the likely skill and training of the person installing the device.	No	---	---	n/a

C.2.27 How will information for safe use be provided

[ID]	Reference Question	Applys	Risk	Probability	Overall
132	Factors that should be considered include whether information will be provided directly to the end user by the manufacturer	No	---	---	n/a
133	Factors that should be considered include will it involve the participation of third parties such as installers	No	---	---	n/a
134	Factors that should be considered include will it involve the participation of third parties such as care providers	No	---	---	n/a
135	Factors that should be considered include will it involve the participation of third parties such as health care professionals	No	---	---	n/a
136	Factors that should be considered include will it involve the participation of third parties such as pharmacists	No	---	---	n/a
137	Factors that should be considered include will it involve whether this will have implications for training	No	---	---	n/a
138	commissioning and handing over to the end user and whether it is likely/possible that installation can be carried out by people without the necessary skills	No	---	---	n/a
139	based on the expected life of the device, whether re-training or re-certification of operators or service personnel would be required	No	---	---	n/a

C.2.28 Will new manufacturing processes need to be established or introduced

[ID]	Reference Question	Applys	Risk	Probability	Overall
140	Factors that should be considered include new technology	No	---	---	n/a
141	Factors that should be considered include new scale of production.	No	---	---	n/a

C.2.29 Is successful application of the medical device critically dependent on human factors

[ID]	Reference Question	Applys	Risk	Probability	Overall
142	such as the user interface	No	---	---	n/a

C.2.29.1 Can the user interface design features contribute to use error

[ID]	Reference Question	Applys	Risk	Probability	Overall
143	Factors that should be considered are user interface design features that can contribute to use error	No	---	---	n/a
144	Examples of interface design features include control and indicators,	No	---	---	n/a
145	Examples of interface design features include symbols used,	No	---	---	n/a
146	Examples of interface design features include ergonomic features	No	---	---	n/a
147	Examples of interface design features include physical design and layout,	No	---	---	n/a
148	Examples of interface design features include hierarchy of operation	No	---	---	n/a
149	Examples of interface design features include menus for software driven devices	No	---	---	n/a
150	Examples of interface design features include visibility of warnings,	No	---	---	n/a
151	Examples of interface design features include audibility of alarms	No	---	---	n/a
152	Examples of interface design features include standardization of colour coding	No	---	---	n/a

C.2.29.2 Is the medical device used in an environment where distractions can cause use error

[ID]	Reference Question	Applys	Risk	Probability	Overall
153	Factors that should be considered include the consequence of use error	Yes	Minor	Occasinal	Acceptable
154	Factors that should be considered include whether the distractions are commonplace	Yes	Minor	Remote	Acceptable
155	Factors that should be considered include whether the user can be disturbed by an infrequent distraction	No	---	---	n/a

C.2.29.3 Does the medical device have connecting parts or accessories

[ID]	Reference Question	Applys	Risk	Probability	Overall
156	Factors that should be considered include the possibility of wrong connections	Yes	Minor	Remote	Acceptable
157	Factors that should be considered include similarity to other products connections,	No	---	---	n/a
158	Factors that should be considered include connection force,	Yes	Minor	Remote	Acceptable
159	Factors that should be considered include feedback on connection integrity	No	---	---	n/a
160	Factors that should be considered include over- and under-tightening.	Yes	Minor	Remote	Acceptable

C.2.29.4 Does the medical device have a control interface

[ID]	Reference Question	Applys	Risk	Probability	Overall
161	Factors that should be considered include spacing,	No	---	---	n/a
162	Factors that should be considered include , coding,	No	---	---	n/a
163	Factors that should be considered include grouping,	No	---	---	n/a
164	Factors that should be considered include mapping,	No	---	---	n/a
165	Factors that should be considered include modes of feedback	No	---	---	n/a
166	Factors that should be considered include modes of blunders	No	---	---	n/a
167	Factors that should be considered include slips	No	---	---	n/a
168	Factors that should be considered include control differentiation	No	---	---	n/a
169	Factors that should be considered include visibility	No	---	---	n/a
170	Factors that should be considered include direction of activation	No	---	---	n/a
171	Factors that should be considered include direction of change	No	---	---	n/a
172	Factors that should be considered include whether the controls are continuous or discrete	No	---	---	n/a
173	Factors that should be considered include the reversibility of settings or actions	No	---	---	n/a

C.2.29.5 Does the medical device display information

[ID]	Reference Question	Applys	Risk	Probability	Overall
174	Factors that should be considered include visibility in various environments	No	---	---	n/a
175	Factors that should be considered include orientation	No	---	---	n/a
176	Factors that should be considered include the visual capabilities of the user	No	---	---	n/a
177	Factors that should be considered include populations and perspectives	No	---	---	n/a
178	Factors that should be considered include clarity of the presented information	No	---	---	n/a
179	Factors that should be considered include units	No	---	---	n/a
180	Factors that should be considered include colour coding	No	---	---	n/a
181	Factors that should be considered include accessibility of critical information	No	---	---	n/a

C.2.29.6 Is the medical device controlled by a menu

[ID]	Reference Question	Applys	Risk	Probability	Overall
182	Factors that should be considered include complexity and number of layers	No	---	---	n/a
183	Factors that should be considered include awareness of state	No	---	---	n/a
184	Factors that should be considered include location of settings	No	---	---	n/a
185	Factors that should be considered include navigation method	No	---	---	n/a
186	Factors that should be considered include number of steps per action	No	---	---	n/a
187	Factors that should be considered include sequence clarity and memorization problems	No	---	---	n/a

[ID]	Reference Question	Applys	Risk	Probability	Overall
188	Factors that should be considered include importance of control function relative to its accessibility and the impact of deviating from specified operating procedures.	No	---	---	n/a

C.2.29.7 Will the medical device be used by persons with special needs

[ID]	Reference Question	Applys	Risk	Probability	Overall
189	Factors that should be considered include the user, their mental and physical abilities, skill and training, ergonomic aspects, the use environment, installation requirements, and the patient`s capability to control or influence the use of the medical device. Special attention should be paid to users with special needs, such as handicapped persons, the elderly and children. Their special needs might include assistance by another person to enable the use of a medical device. Is the medical device intended to be used by individuals with various skill levels and cultural backgrounds	No	---	---	n/a

C.2.29.8 Can the user interface be used to initiate user actions

[ID]	Reference Question	Applys	Risk	Probability	Overall
190	Factors that should be considered include the possibility of initiatinig a deliberate action for the user to enter a controlled operation mode, which enlarges the risks for the patient and which creates awareness for the user for this condition.	No	---	---	n/a

C.2.3 Is the medical device intended to be in contact with the patient or other persons

[ID]	Reference Question	Applys	Risk	Probability	Overall
20	Factors that should be considered include the nature of the intended contact	No	---	---	n/a
21	Factors that should be considered include the nature of the intended contact surface contact	No	---	---	n/a
22	Factors that should be considered include the nature of the intended contact invasive contact	No	---	---	n/a
23	Factors that should be considered include the nature of the intended the period of contact	No	---	---	n/a
24	Factors that should be considered include the nature of the intended the frequency of contact	No	---	---	n/a

C.2.30 Does the medical device use an alarm system

[ID]	Reference Question	Applys	Risk	Probability	Overall
191	Factors that should be considered are the risk of false alarms	No	---	---	n/a
192	Factors that should be considered are the risk of missing alarms	No	---	---	n/a
193	Factors that should be considered are the risk of disconnected alarm systems	No	---	---	n/a
194	Factors that should be considered are the risk unreliable remote alarm systems	No	---	---	n/a

[ID]	Reference Question	Applys	Risk	Probability	Overall
195	Factors that should be considered are the medical staffs possibility of understanding how the alarm system works	No	---	---	n/a

C.2.31 In what ways might the medical device be deliberately misused

[ID]	Reference Question	Applys	Risk	Probability	Overall
196	Factors that should be considered are incorrect use of connectors	No	---	---	n/a
197	Factors that should be considered are disabling safety features or alarms	No	---	---	n/a
198	Factors that should be considered are neglect of manufacturer`s recommended maintenance	Yes	Minor	Remote	Acceptable

C.2.32 Does the medical device hold data critical to patient care

[ID]	Reference Question	Applys	Risk	Probability	Overall
199	Factors that should be considered include the consequence of the data being modified	No	---	---	n/a
200	Factors that should be considered include the consequence of the data being corrupted.	No	---	---	n/a

C.2.33 Is the medical device intended to be mobile or portable

[ID]	Reference Question	Applys	Risk	Probability	Overall
201	Factors that should be considered are the necessary grips,	No	---	---	n/a
202	Factors that should be considered are the necessary handles,	No	---	---	n/a
203	Factors that should be considered are the necessary wheels,	No	---	---	n/a
204	Factors that should be considered are the necessary, brakes,	No	---	---	n/a
205	Factors that should be considered are, mechanical stability	No	---	---	n/a
206	Factors that should be considered are,durability	No	---	---	n/a

C.2.34 Does the use of the medical device depend on essential performance

[ID]	Reference Question	Applys	Risk	Probability	Overall
207	Factors that should be considered are the characteristics of the output of life-supporting devices	No	---	---	n/a
208	Factors that should be considered are the operation of an alarm	No	---	---	n/a

C.2.4 What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device

[ID]	Reference Question	Applys	Risk	Probability	Overall
25	Factors that should be considered include compatibility with relevant substances	No	---	---	n/a
26	Factors that should be considered include compatibility with tissues	No	---	---	n/a
27	Factors that should be considered include compatibility with body fluids	No	---	---	n/a

[ID]	Reference Question	Applys	Risk	Probability	Overall
28	whether characteristics relevant to safety are known	No	---	---	n/a
29	is the device manufactured utilizing materials of animal origin	No	---	---	n/a

C.2.5 Is energy delivered to or extracted from the patient

[ID]	Reference Question	Applys	Risk	Probability	Overall
30	Factors that should be considered include the type of energy transferred	Yes	Minor	Remote	Acceptable
31	Factors that should be considered include the type of energy its control	No	---	---	n/a
32	Factors that should be considered include the type of energy its quality	No	---	---	n/a
33	Factors that should be considered include the type of energy its intensity	No	---	---	n/a
34	Factors that should be considered include the type of energy its duration	No	---	---	n/a
35	Factors that should be considered include whether energy levels are higher than those currently used for similar devices	No	---	---	n/a

C.2.6 Are substances delivered to or extracted from the patient

[ID]	Reference Question	Applys	Risk	Probability	Overall
36	Factors that should be considered include whether the substance is delivered	No	---	---	n/a
37	Factors that should be considered include whether the substance is extracted	No	---	---	n/a
38	Factors that should be considered include whether it is a single substance	No	---	---	n/a
39	Factors that should be considered include whether it is a range of substances	No	---	---	n/a
40	Factors that should be considered include maximum transfer rates and control thereof	No	---	---	n/a
41	Factors that should be considered include minimum transfer rates and control thereof	No	---	---	n/a

C.2.7 Are biological materials processed by the medical device for subsequent

[ID]	Reference Question	Applys	Risk	Probability	Overall
43	re-use,	No	---	---	n/a
44	transfusion	No	---	---	n/a
45	transplantation	No	---	---	n/a

C.2.8 Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable

[ID]	Reference Question	Applys	Risk	Probability	Overall
46	Factors that should be considered include whether the medical device is intended for single use	No	---	---	n/a

[ID]	Reference Question	Applys	Risk	Probability	Overall
47	Factors that should be considered include whether the medical device is intended for re-use packaging	No	---	---	n/a
48	Factors that should be considered include shelf-life issues	No	---	---	n/a
49	Factors that should be considered include limitation on the number of re-use cycles	No	---	---	n/a
50	Factors that should be considered include method of product sterilization	No	---	---	n/a
51	Factors that should be considered include the impact of other sterilization methods not intended by the manufacturer	No	---	---	n/a

C.2.9 Is the medical device intended to be routinely cleaned and disinfected by the user

[ID]	Reference Question	Applys	Risk	Probability	Overall
52	Factors that should be considered include the types of cleaning or disinfecting agents to be used	Yes	Minor	Remote	Acceptable
53	Factors that should be considered include any limitations on the number of cleaning cycles.	Yes	Minor	Remote	Acceptable
54	Factors that should be considered include The design of the Medical device can influence the effectiveness of routine cleaning and disinfection	Yes	Minor	Remote	Acceptable
55	Factors that should be considered include the effect of cleaning and disinfecting agents on the safety or performance of the device.	No	---	---	n/a

D.2 Energy hazards and contributory factors

[ID]	Reference Question	Applys	Risk	Probability	Overall
222	Mechanical force	No	---	---	n/a
223	Gravity Falling	Yes	Minor	Remote	Acceptable
224	Suspended masses	No	---	---	n/a
225	Stored energy	No	---	---	n/a
226	Torsion,Shear & Tensile	No	---	---	n/a
227	High Pressure Fluid injection	No	---	---	n/a
230	Moving parts	No	---	---	n/a
231	Moving & positioning patient	No	---	---	n/a
232	Unintended motion	No	---	---	n/a
233	Patient support failure	No	---	---	n/a
234	Pressure vessel rupture	No	---	---	n/a
235	Acoustic pressure	No	---	---	n/a
236	Ultrasonic energy	No	---	---	n/a
237	Infrasound energy	No	---	---	n/a

D.3 Toxic hazards and contributory factors

[ID]	Reference Question	Applys	Risk	Probability	Overall
241	Bio-contamination	No	---	---	n/a
242	Bacteria	No	---	---	n/a

[ID]	Reference Question	Applys	Risk	Probability	Overall
243	Viruses	No	---	---	n/a
244	Other agents prions	No	---	---	n/a
245	Bio-incompatibility	No	---	---	n/a
246	Incorrect formulation chemical composition	No	---	---	n/a
247	Toxicity	No	---	---	n/a
248	Allergenicity/ irritancy	No	---	---	n/a
249	Mutagenicity	No	---	---	n/a
250	Oncogenicity	No	---	---	n/a
251	Carcinogenicity	No	---	---	n/a
252	Re and/or cross infection	No	---	---	n/a
253	Pyrogenicity	No	---	---	n/a

D.3.12 hygienic standards

[ID]	Reference Question	Applys	Risk	Probability	Overall
254	Degradation	No	---	---	n/a
255	Chemical	No	---	---	n/a
256	Acids or Alkalis	No	---	---	n/a
257	Contaminates	No	---	---	n/a
258	Processing aids	No	---	---	n/a
260	Testing aids	No	---	---	n/a
261	Medical gases	No	---	---	n/a
262	Anaesthetic products	No	---	---	n/a

D.4 Electromagnetic fields

[ID]	Reference Question	Applys	Risk	Probability	Overall
268	Operation outside prescribed environmental conditions	No	---	---	n/a
270	Accidental mechanical damage	No	---	---	n/a
271	Contamination due to waste products and/or device disposal	No	---	---	n/a

D.5

[ID]	Reference Question	Applys	Risk	Probability	Overall
274	Volume	No	---	---	n/a
275	Supply of medical gases	No	---	---	n/a
276	Pressure	Yes	Minor	Remote	Acceptable
277	Supply of anaesthetic agents	No	---	---	n/a

D.6 Hazards related to the use of the medical device and contributory factors

[ID]	Reference Question	Applys	Risk	Probability	Overall
279	Inadequate operating instructions	Yes	Minor	Remote	Acceptable
280	Inadequate description of performance	Yes	Minor	Remote	Acceptable
281	Inadequate specification of intended use	No	---	---	n/a

[ID]	Reference Question	Applys	Risk	Probability	Overall
282	Inadequate disclosure of limitations	No	---	---	n/a
283	Inadequate specification of accessories	No	---	---	n/a
284	Inadequate specification of pre-use checks	No	---	---	n/a
285	Over-complicated operating instructions	Yes	Minor	Remote	Acceptable
286	Inadequate specification of service and maintenance	No	---	---	n/a
287	Use by unskilled / untrained personnel	Yes	Minor	Remote	Acceptable
288	Reasonable foreseeable misuse	No	---	---	n/a
289	Insufficient warning of side effects	No	---	---	n/a
290	Incorrect measurement and other metrological aspects	No	---	---	n/a
291	Inadequate warnings of hazards likely with re-use of single use devices	No	---	---	n/a
292	Misrepresentation of results	No	---	---	n/a
293	Incompatibility with consumables / accessories / other devices	No	---	---	n/a
294	Sharp edges or points	No	---	---	n/a

D.7 Mistakes judgement errors

[ID]	Reference Question	Applys	Risk	Probability	Overall
295	Mistakes & judgement errors	No	---	---	n/a
296	Incorrect or inappropriate output or functionality	No	---	---	n/a
297	Erroneous data transfer	No	---	---	n/a
298	Loss or deterioration in function	No	---	---	n/a
301	Rule based failure	No	---	---	n/a
302	Knowledge based failure	No	---	---	n/a
303	Routine violation	No	---	---	n/a
304	Violation or abbreviation of instructions, procedures etc	No	---	---	n/a
308	Misrepresentation of results	No	---	---	n/a
311	Controversial modes or mappings as compared to existing equipment	No	---	---	n/a

D.8

[ID]	Reference Question	Applys	Risk	Probability	Overall
317	Loss of mechanical integrity	No	---	---	n/a
318	Inadequate packaging contamination and / or deterioration of the device	No	---	---	n/a
320	Deterioration in function gradual occlusion of fluid / gas path or change in resistance to flow, electrical conductivity as a result of repeated use	No	---	---	n/a

Risk ISO 14971 : 2012 Summary

Tom Thumb Risk Assessment Document Summary Applicable questions

Reference Question	Applys	Risk	Risk Probability	Overall Risk	Assessed By	Assessed On	Risk Completed
10	Yes	Minor	Remote	Acceptable	John Lamb	25/02/14	Yes
11	Yes	Serious	Remote	Acceptable	John Lamb	25/02/14	Yes
30	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
52	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
53	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
54	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
59	Yes	Critical	Remote	Acceptable	Derek Lamb	25/02/14	Yes
102	Yes	Minor	Remote	Acceptable	Derek Lamb	24/02/14	Yes
103	Yes	Minor	Remote	Acceptable	Derek Lamb	24/02/14	Yes
105	Yes	Serious	Remote	Acceptable	Derek Lamb	24/02/14	Yes
108	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
110	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
129	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
153	Yes	Minor	Occasinal	Acceptable	Derek Lamb	21/02/14	Yes
154	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
156	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
158	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
160	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
198	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
223	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
276	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
278	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
279	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
280	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
285	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes
287	Yes	Minor	Remote	Acceptable	Derek Lamb	21/02/14	Yes